

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF NEVADA  
3 BEFORE THE HONORABLE MIRANDA DU, DISTRICT JUDGE  
4 ---o0o---

4 AMARIN PHARMA, INC., and :  
5 AMARIN PHARMACEUTICALS :  
6 IRELAND LIMITED, :  
7 : No. 2:16-cv-02525-MMD-NJK  
8 Plaintiffs, :  
9 : January 17, 2020  
10 -vs- :  
11 : Reno, Nevada  
12 HIKMA PHARMACEUTICALS USA :  
13 INC., et al., : Volume 4  
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08:18:19 1 RENO, NEVADA, FRIDAY, JANUARY 17, 2019, 8:35 A.M.

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08:18:38 3

08:35:24 4 THE COURT: Good morning. Please be seated.

08:35:34 5 All right. Counsel, are you ready to call the

08:35:37 6 next witness for defendants?

08:35:38 7 MR. REIG-PLESSIS: Your Honor, Eimeric Reig for

08:35:44 8 the defendants.

08:35:45 9 Before we call our next witness, we have just

08:35:48 10 one housekeeping matter. There is an exhibit that was

08:35:51 11 discussed during the direct examination of Dr. Sheinberg that

08:35:56 12 we inadvertently did not move into evidence. My understanding

08:36:00 13 had been mistakenly that it was already in evidence.

08:36:02 14 We conferred with plaintiff's counsel and

08:36:04 15 understand there's no objection to its admittance at this

08:36:08 16 time, although I'll let them confirm. But we would move into

08:36:11 17 evidence DX 1960 at this time, if that's all right.

08:36:14 18 MS. KEANE: No objection, Your Honor.

08:36:15 19 THE COURT: All right. DX 1960 is admitted.

08:36:15 20 (Defendant's Exhibit 1960 received in

08:36:15 21 evidence.)

08:36:21 21 MR. REIG-PLESSIS: Thank you.

08:36:30 22 MS. HUTTNER: Your Honor, defendant's call

08:36:36 23 Dr. Edward Fisher.

24 THE CLERK: Do you have binders for him to use?

25 MS. HUTTNER: Yes.

1 EDWARD A. FISHER, M.D.,  
2 called as a witness on behalf of the Defendant,  
3 was sworn and testified as follows:

08:37:21 THE CLERK: Please be seated.  
08:37:21

08:37:23 4 State for the record your full name and spell  
08:37:25 5 your last name.

08:37:26 6 THE WITNESS: Full name is Edward A. Fisher,  
08:37:31 7 F-i-s-h-e-r.

08:37:53 8 MS. HUTTNER: Good morning, Dr. Fisher.

08:37:55 9 THE WITNESS: Good morning.

08:37:55 10 DIRECT EXAMINATION

08:37:55 11 BY MS. HUTTNER:

08:37:56 12 Q Dr. Fisher, where are you currently employed?

08:37:59 13 A The New York University School of Medicine.

08:38:02 14 Q And what is your position there?

08:38:03 15 A I am the Leon H. Charney Professor of Cardiovascular  
08:38:05 16 Medicine.

08:38:06 17 Q Now, you are testifying here as a rebuttal witness for --  
08:38:09 18 or actually you're testifying here on behalf of both  
08:38:12 19 defendants in this case, Hikma and Dr. Reddy's?

08:38:15 20 A I am.

08:38:15 21 Q And specifically you're testifying in response to the  
08:38:18 22 opinions expressed by Amarin's experts, Drs. Ismail and Mason  
08:38:24 23 and, to a certainly extent, Dr. Toth, concerning certain  
08:38:28 24 alleged objective evidence of nonobviousness in this case?

08:38:32 25 A I am.

08:38:32 1 Q And am I correct in understanding that Dr. Ismail's  
08:38:42 2 opinions relate to alleged objective evidence of  
08:38:46 3 nonobviousness that he discusses in his report?

08:38:48 4 A Yes.

08:38:48 5 Q And am I also correct in understanding that Dr. Mason's  
08:38:52 6 opinions relate to the beneficial -- what he calls the  
08:38:55 7 beneficial physiological properties of purified EPA which he  
08:39:00 8 claims were unknown in 2008 and were likely responsible for  
08:39:06 9 the cardiac benefits observed in the REDUCE-IT study?

08:39:06 10 A Yes.

08:39:07 11 Q Now, Dr. Fisher, did you work with the attorneys today to  
08:39:12 12 prepare some slides to assist you with your presentation?

08:39:15 13 A I did.

08:39:15 14 Q And before we get into your substantive testimony, I want  
08:39:20 15 to ask you some questions about your background and  
08:39:21 16 experience.

08:39:22 17 A Okay.

08:39:23 18 MS. HUTTNER: So let's start, Mr. Gross, if you  
08:39:26 19 can bring up DX 2295.

08:39:26 20 BY MS. HUTTNER:

08:39:30 21 Q Can you identify DX 2295 for the record.

08:39:33 22 A That's my CV.

08:39:35 23 MS. HUTTNER: Your Honor, we would move DX 2295  
08:39:39 24 into evidence.

08:39:39 25 MR. SIPES: No objection, Your Honor.

08:39:41 1 THE COURT: DX 2295 is admitted.

08:39:41 2 (Defendant's Exhibit 2295 received in  
08:39:41 evidence.)

08:39:41 3 BY MS. HUTTNER:

08:39:45 4 Q All right. So let's start your education.

08:39:47 5 MS. HUTTNER: Mr. Gross, if you could blow that  
08:39:49 6 up, please. Can we get the whole thing on one?

08:39:49 7 BY MS. HUTTNER:

08:40:01 8 Q Okay. So starting after your graduation from  
08:40:07 9 undergraduate in 1971, can you describe your educational  
08:40:10 10 background to the Court.

08:40:11 11 A Yes. In 1975, I received my medical degree from NYU  
08:40:18 12 School of Medicine, and then, in 1978, after my residency at  
08:40:23 13 Duke, I went over to the University of North Carolina in  
08:40:26 14 Chapel Hill and studied epidemiology and received a master's  
08:40:31 15 of public health.

08:40:32 16 And then from there I went up to MIT and received a  
08:40:36 17 Ph.D in the area of lipoprotein metabolism. My thesis advisor  
08:40:43 18 was Dr. Jan Breslow who subsequently became a president of the  
08:40:49 19 American Heart Association.

08:40:51 20 The MA degree was actually required to be given to  
08:40:59 21 me when I was a professor at Oxford so I would be qualified to  
08:40:59 22 teach their undergraduates.

08:41:00 23 Q And can you explain why you pursued the degrees that you  
08:41:04 24 pursued after you received your medical degree.

08:41:09 25 A My parents asked me that question, yeah.

08:41:10 1 The clinical training when I was a resident, during  
08:41:15 2 that time I realized I was more interested in an academic  
08:41:21 3 research career in medicine, and epidemiology is the basis of  
08:41:26 4 designing and interpreting clinical trials, and I thought this  
08:41:29 5 would be good education going forward to help me in my own  
08:41:34 6 work and evaluating that of others.

08:41:37 7 And while I was in public health school, I kept in  
08:41:41 8 touch with my mentor at Duke who was chief of the metabolism  
08:41:46 9 division and pointed out to me this program at MIT for people  
08:41:51 10 like me who are MDs and had done residencies and were  
08:41:55 11 interested in metabolism, and I applied and was accepted.

08:41:58 12 And in a survey course of different areas of  
08:42:01 13 metabolism, Professor Breslow gave his lecture on VLDL  
08:42:06 14 metabolism, and I decided to enter his lab to do my Ph.D  
08:42:11 15 training, and this has set in motion the major interests that  
08:42:16 16 I have pursued in my independent career.

08:42:19 17 Q Now, we've heard a little bit about, I think, VLDL in  
08:42:24 18 this case, but what -- can you just explain what that is.

08:42:28 19 A VLDL is the lipoprotein particle assembled in the liver  
08:42:32 20 that is then secreted and transports to the different cells in  
08:42:37 21 our body both the cholesterol it carries and triglycerides as  
08:42:42 22 well.

08:42:43 23 Q All right. What about your academic experience and your  
08:42:46 24 professional experience prior to NYU?

08:42:50 25 MS. HUTTNER: Mr. Gross, can we go down to that

on the CV, please.

THE WITNESS: Prior to NYU, I was a professor of medicine in the Cardiology Division at the Mount Sinai School of Medicine. I was head of the Lipoprotein Research Section of the Cardiovascular Research Institute which was headed by Dr. Valentin Fuster, another former president of the American Heart Association.

And before that, I was in Philadelphia. I was an Associate Professor of Biochemistry where I did my laboratory research program but also had clinical appointments in pediatrics and medicine.

And it was there that I started a family-based clinic for the treatment of lipid disorders. I partnered with people in endocrinology in the Department of Medicine, and I would see the kids, and they would see the adults, and we would formulate a plan for the whole family together.

Prior to the Medical College of Pennsylvania, I was at the University of Pennsylvania specifically at the Genetics Division of the Children's Hospital of Philadelphia.

I was recruited there by Jean Cortner, the late Jean Cortner, who had started a lipid treatment and research program at the hospital, and, given my previous training with Professor Breslow, thought I would be a good recruit for both the research part of the program as well as the clinical. So that was my first faculty job.

08:44:32 1 MS. HUTTNER: Can I have DX 9.108, please,  
08:44:32 2 Mr. Gross.

08:44:32 3 BY MS. HUTTNER:

08:44:43 4 Q This slide contains some information that's excerpted  
08:44:46 5 from your CV; is that correct?

08:44:48 6 A Yes.

08:44:48 7 Q Can you explain -- I think most of these relate to your  
08:44:53 8 current position at NYU; is that correct?

08:44:55 9 A Yes, it does.

08:44:56 10 Q Can you explain what the Leon H. Carney Professor of  
08:45:00 11 Cardiovascular Medicine is at NYU.

08:45:03 12 A Yes, that's an endowed chair. We heard a little bit  
08:45:06 13 about endowed chairs, I think, from Dr. Budoff.

08:45:10 14 An endowed professorship is a special distinction  
08:45:15 15 that is conferred on people who are recognized with special  
08:45:16 16 expertise, in my case, in cardiovascular medicine.

08:45:21 17 I also direct the preclinical research program in  
08:45:27 18 vascular biology and disease which refers to cholesterol,  
08:45:32 19 triglyceride, metabolism, atherosclerosis.

08:45:37 20 I have also appointments within cardiology, that's  
08:45:41 21 my primary home at NYU. I also have what are called secondary  
08:45:47 22 appointments in pediatrics and cell biology.

08:45:50 23 In order to be a graduate school mentor, you need an  
08:45:57 24 appointment in a basic science department so cell biology is  
08:45:57 25 one of those for me.

08:45:58 1 And I was the -- still am, the founding director,  
08:46:04 2 I'm the former director of the Preventive Cardiology Center at  
08:46:07 3 NYU which is a component of the Cardiology Division.

08:46:10 4 I transitioned this after 16 years of leading it to  
08:46:10 5 a career faculty member, passing the torch over this past  
08:46:20 6 year, and I assumed the position of the Director of  
08:46:22 7 Translational Research for the center.

08:46:25 8 And then the last thing that's listed is my ongoing  
08:46:29 9 relationship in cardiovascular medicine at the University of  
08:46:32 10 Oxford.

08:46:33 11 As we already noted, I was what's called the Eastman  
08:46:36 12 Professor at Oxford, and my appointment there was in the  
08:46:41 13 cardiovascular medicine department, and after I did my term, I  
08:46:44 14 was awarded a visiting position which has resulted in a number  
08:46:48 15 of research paper collaborations, as well as my co-authoring  
08:46:52 16 the chapter on atherosclerosis in the Oxford Textbook of  
08:46:57 17 Medicine.

08:46:58 18 Q And is the appointment at the University of Oxford, is  
08:47:02 19 that considered an honor for a person in your field?

08:47:04 20 A Yes, it is. It's -- it has to be approved on their end,  
08:47:09 21 and there has to be perceived some value in continuing the  
08:47:15 22 interaction.

08:47:16 23 In fact, one the things that has happened since then  
08:47:20 24 is that I was awarded from the Royal Society, the British  
08:47:24 25 Royal Society, an exchange grant to pay for travel back and

08:47:31 1 forth to keep collaborating, as well as trainees to go between  
08:47:36 2 laboratories to learn from both institutions.

08:47:39 3 Q All right. Now, you've mentioned on here that you are  
08:47:43 4 the -- you were the founding director of the Center for the  
08:47:47 5 Prevention of Cardiovascular Disease; is that right?

08:47:50 6 A That's correct, when I came to NYU in 2003.

08:47:52 7 Q Now, your residency, your certification is in pediatrics;  
08:47:56 8 is that correct?

08:47:56 9 A Yes.

08:47:56 10 Q Can you explain how you went from -- how you became the  
08:48:00 11 head of preventive cardiology at NYU.

08:48:03 12 A Yes, I can.

08:48:04 13 I mentioned before that within pediatrics, I had  
08:48:10 14 experienced an interest in disorders of lipid metabolism that  
08:48:15 15 actually started in my residency because, again, my mentor was  
08:48:19 16 head of metabolism and had a very strong unit at Duke.

08:48:22 17 And this was reinforced actually in public health  
08:48:26 18 school as well where I was housed in the component that was  
08:48:29 19 led by the late Herman Tyroler who was well-known in the -- in  
08:48:36 20 the cardiovascular disease world as being the principal  
08:48:42 21 investigator of one of the first intervention trials, the  
08:48:47 22 lipid research center trials in the '70s.

08:48:51 23 And so when I went to my first, as we would say,  
08:48:53 24 real job at Penn, I entered, as you heard, the component of  
08:49:00 25 the designated lipid heart research center.

08:49:06 1 And so -- and when I was at the Medical College of  
08:49:08 2 Pennsylvania, did the family clinic. So I've had strong  
08:49:12 3 clinical interest.

08:49:13 4 But when I got to Mount Sinai, Dr. Fuster, my boss,  
08:49:18 5 said that it would be a good opportunity for me to expand my  
08:49:24 6 expertise from the pediatric age group into the adult.

08:49:28 7 And I already had an appointment in cardiology at  
08:49:33 8 Mount Sinai so it was easy to arrange this because the head of  
08:49:38 9 preventive cardiology at that time, Professor Donald Smith,  
08:49:42 10 was a well-recognized expert in preventive cardiology and took  
08:49:46 11 me for advanced training, on-the-job training, for about two  
08:49:52 12 years.

08:49:53 13 And then when he felt I was sufficiently qualified,  
08:49:57 14 I now began my own practice, an outpatient practice in  
08:50:01 15 preventive cardiology, focused on adults at Mount Sinai.

08:50:05 16 And I went through the accreditation process to be  
08:50:08 17 appointed to the medical staff in that area at Mount Sinai,  
08:50:12 18 and I have been continued to be credentialed at NYU for this  
08:50:16 19 purpose as well.

08:50:17 20 Q We heard a little bit, I think, from Dr. Budoff about  
08:50:19 21 what preventive cardiology -- what that field involves. But  
08:50:23 22 at NYU, what does the Preventive Cardiology Division, what  
08:50:27 23 kinds of things does that division do?

08:50:29 24 A Well, it has a wide range, from basic research projects  
08:50:36 25 that people like me do, to clinical research projects, and

then direct clinical care, both inpatient and outpatient.

And the goal for the clinical component, the clinical care, is to manage the modifiable risk factors for heart disease.

So that some of our patients have not had an event, like a heart attack or a stroke, and so they are in what's called the primary prevention group, but those who have had an event, were documented, coronary heart disease in particular, they, of course, are in the secondary prevention group.

So the major risk factors are lipids, sugar, and blood pressure. So we focus on those.

We are a referral center so we do tend to get some more difficult cases from referring physicians that are typical, and we also get a lot of self-referrals because, according to the NYU webmaster, our website is popular so people will self-refer themselves to us as well.

Q You said you were the Director of Translational Research in the Cardiology Division at NYU?

A In the center.

Q The center.

A The prevention center.

Q Can you explain what translational research is, please.

A That's a general term. It's widely used to take the discoveries that are preclinical to the clinic.

So as you know, your medical treatment is only as

08:52:08 1 good as yesterday's research, and so for advances in medical  
08:52:13 2 treatment, we have to translate discoveries that we make in  
08:52:16 3 more typical model systems such as cells and animals.

08:52:21 4 And so I oversee a portfolio of projects that we  
08:52:27 5 hope to attract funding to do some limited local clinical  
08:52:33 6 trials.

08:52:33 7 And then the usual thing that happens after that, if  
08:52:36 8 you have something that does show some success, the school  
08:52:40 9 looks for partners, outside partners, to invest to make this a  
08:52:44 10 larger study.

08:52:45 11 Q And how often do preclinical discoveries or experiments  
08:52:50 12 translate into something that you can use in the clinic?

08:52:53 13 A It's rare. It's rare.

08:52:57 14 Q You mentioned that you do research currently.

08:52:58 15 A I do.

08:52:59 16 Q And you've done research throughout your professional  
08:53:02 17 career?

08:53:02 18 A I have.

08:53:03 19 Q What kind of -- what is your research focused on, what  
08:53:07 20 topics?

08:53:08 21 A Lipoprotein metabolism and atherosclerosis.

08:53:12 22 MS. HUTTNER: And if we could call up DDX 9.112.

08:53:12 23 BY MS. HUTTNER:

08:53:17 24 Q And, again, Dr. Fisher, this is taken from your CV, the  
08:53:21 25 information on DDX 9.112?

08:53:23 1 A Yes.

08:53:23 2 Q Can you describe what is shown on this slide.

08:53:27 3 A These are two examples of current grants that I direct,  
08:53:32 4 and I pulled these out because they're in the areas that are  
08:53:35 5 relevant to the issues we'll be discussing today.

08:53:39 6 The first is a federal grant from the National  
08:53:45 7 Heart, Lung, Blood Institute, NHLBI, which is a component of  
08:53:50 8 the National Institutes of Health. This -- the total funding  
08:53:54 9 over five years is 12 and-a-half million dollars.

08:53:59 10 The topics as you see listed there are macrophage,  
08:54:05 11 macrophage dysfunction in obesity, diabetes and  
08:54:10 12 atherosclerosis.

08:54:10 13 We'll hear more about macrophages later, but they  
08:54:14 14 are the central inflammatory cell of an atherosclerotic plaque  
08:54:16 15 that is -- causes the danger of a heart attack.

08:54:21 16 I am the overall director of that project, of that  
08:54:26 17 program project grant, and I also have my own -- within it, my  
08:54:29 18 own research project.

08:54:32 19 These are carved up into different areas. So I am  
08:54:35 20 director of Project 1, and the overall director means that I'm  
08:54:39 21 also head of Core A which is always the administrative core of  
08:54:44 22 a federal PPG is what it's called, program project grant.

08:54:52 23 The second grant is actually from the American Heart  
08:54:58 24 Association. It was just started actually this month.

08:55:01 25 The AHA has identified diabetes as a particularly

08:55:07 1 important problem to focus more attention on, and so we were  
08:55:14 2 one of four centers in the country who were funded to take a  
08:55:21 3 multifaceted approach to the problem of atherosclerosis and  
08:55:26 4 heart disease in people with diabetes. I am head of the basic  
08:55:31 5 science project.

08:55:32 6 We also have a clinical project headed by Dr. --  
08:55:37 7 well, headed by a physician at Mount Sinai. It's hard to  
08:55:42 8 spell the name. It's Giannerelli; G-i-a-n-n-e-r-e-l-l-i.

08:55:48 9 And we have a clinical project at NYU headed by  
08:55:53 10 Dr. Jeffrey Berger, and this started -- this is a four-year  
08:55:57 11 grant, and it's total funding of about \$4 million.

08:56:00 12 Q Is it competitive to get grants?

08:56:03 13 A Very competitive.

08:56:04 14 Q Does your CV also describe the publications that you have  
08:56:09 15 had in relation to your research?

08:56:11 16 A Yes, it does.

08:56:12 17 Q How many publications approximately are listed on your  
08:56:15 18 CV?

08:56:15 19 A A little over 300.

08:56:17 20 Q And do any of your publications relate to triglycerides  
08:56:23 21 or omega-3 fatty acids?

08:56:25 22 A Yes, they do. I've been funded since 1993 to study,  
08:56:31 23 among other things, how fish oils, fatty acids, DHA and EPA,  
08:56:36 24 regulate the production of VLDL and the triglycerides that it  
08:56:42 25 carries in the blood.

08:56:45 1 Q Have you prepared a slide that highlights some of your  
08:56:45 2 publications that you believe are particularly relevant to  
08:56:49 3 this case?

08:56:49 4 A I did.

08:56:50 5 MS. HUTTNER: Can I have DDX 9.114.

08:56:50 6 BY MS. HUTTNER:

08:56:55 7 Q Can you explain what's presented on this slide,  
08:56:58 8 Dr. Fisher.

08:56:59 9 A Okay. So these are just some samples out of the 300 or  
08:57:02 10 so, and I chose them -- I'll go through -- not in great  
08:57:07 11 detail, of course, but some highlights.

08:57:09 12 The very first one listed is my first paper in the  
08:57:14 13 area of the effect of fatty acids on the levels of VLDL  
08:57:25 14 cholesterol and triglycerides in humans.

08:57:30 15 This was a clinical study that I undertook for my  
08:57:32 16 Ph.D working under Professor Breslow, so just -- it's to  
08:57:35 17 demonstrate a long-term interest and experience and the  
08:57:38 18 effects of fatty acids on lipoprotein metabolism.

08:57:39 19 Then I featured some of the work that focused on EPA  
08:57:45 20 and DHA through the years, and sort of a third of the way  
08:57:52 21 down, the paper, first author, Parathath, P-a-r-a-t-h-a-t-h,  
08:58:00 22 this was actually not only my first work in diabetes and  
08:58:05 23 atherosclerosis using a mouse model, this was the first model  
08:58:11 24 in the literature, the research literature, that showed that  
08:58:13 25 we can recapitulate in mice the same problem that's seen in

08:58:17 1 people with diabetes that, in spite of lipid lowering, it's  
08:58:22 2 hard to resolve the inflammation in an atherosclerotic plaque.

08:58:28 3 So in this case we decided that human beings were a  
08:58:32 4 good model for mice, and we then proceeded on through the  
08:58:35 5 years to learn more from this model.

08:58:37 6 As you can see, it's published in the journal -- the  
08:58:39 7 official journal of American Diabetes Association called  
08:58:44 8 *Diabetes*.

08:58:44 9 And then most recently there is a paper there,  
08:58:48 10 Barrett, B-a-r-r-e-t-t, et al., this was just published in the  
08:58:54 11 journal *Circulation*. We've heard about this. This is the  
08:58:58 12 most prestigious journal of the American Heart Association.

08:59:04 13 It's also about diabetes, atherosclerosis,  
08:59:06 14 inflammation, HDL, covers a number of topics, and it has  
08:59:12 15 received wide recognition as reflected by an editorial by Dan  
08:59:18 16 Rader who is one of the major preventive cardiologists in the  
08:59:22 17 U.S. He wrote an editorial in the journal about the  
08:59:25 18 importance of this work.

08:59:26 19 I included two other papers just to show that I am  
08:59:32 20 considered an expert in the inflammatory processes that occur  
08:59:37 21 in atherosclerosis in the plaques and the arteries, and one is  
08:59:41 22 in a well-known journal, it's a part of the *Nature* family of  
08:59:49 23 journals. *Nature* reviews cardiology, and the other is in a  
08:59:52 24 relatively new review journal *Frontiers in Cardiovascular*  
08:59:57 25 *Medicine*?

08:59:57 1 Q Have you received any honors or recognition in your  
09:00:01 2 career for your work in lipidology and preventive cardiology?

09:00:06 3 A I have.

09:00:06 4 Q And are those described in your CV as well?

09:00:09 5 A They are.

09:00:10 6 MS. HUTTNER: Can I have DDX 9.110, please.

09:00:10 7 BY MS. HUTTNER:

09:00:14 8 Q Can you explain what's presented on this slide.

09:00:16 9 A These are some examples that I think are most relevant,  
09:00:19 10 again, to the issues that we'll be discussing.

09:00:22 11 On the top is the distinguished achievement award of  
09:00:27 12 the American Heart Association given by the council that is  
09:00:30 13 most related to atherosclerosis and lipoprotein metabolism.  
09:00:37 14 This is the ATVB Council, arteriosclerosis, thrombosis,  
09:00:43 15 vascular biology.

09:00:43 16 And as I noted, or I might have already said, this  
09:00:46 17 is highest honor the council gives, and it's in recognition of  
09:00:46 18 my contributions to the field of lipoprotein metabolism and  
09:00:50 19 atherosclerosis.

09:00:52 20 We also heard about the National Lipid Association  
09:00:57 21 from other witnesses. They gave me the lifetime achievement  
09:01:02 22 award, and the citation reads -- it's one of my favorites --  
09:01:06 23 remarkable accomplishments in the field of lipidology.

09:01:10 24 The next two involved organizing and chairing two of  
09:01:16 25 the major conferences in atherosclerosis.

09:01:20 1 They cover both clinical research and basic  
09:01:24 2 preclinical research topics, the Keystone series of research  
09:01:30 3 symposia, as well as the Gordon conference, a series going on  
09:01:36 4 for many years, they are in many different areas, and they're  
09:01:39 5 considered in any field to be the most prestigious in those  
09:01:44 6 areas, and I was very honored to be asked to organize and  
09:01:48 7 chair these two research conferences in atherosclerosis.

09:01:53 8 I mentioned before the George Eastman Professorship.  
09:01:57 9 This was a program started in the '20s, by George Eastman of  
09:02:04 10 Eastman-Kodak.

09:02:04 11 One of the first Eastman Professors, they're not all  
09:02:08 12 scientists, I should say, I point out, since we're in a  
09:02:08 13 courtroom, is Justice Felix Frankfurter before he went to the  
09:02:08 14 Supreme Court.

09:02:17 15 And of the scientists, 12 of my predecessors won the  
09:02:21 16 Nobel Prize. So this is considered one of the most distinguished  
09:02:25 17 types of faculty appointments not only at Oxford but in  
09:02:29 18 universities in general.

09:02:30 19 And the last two are concerning again my activities  
09:02:36 20 in the field, or recognition for my expertise in preventive  
09:02:42 21 cardiology and lipoprotein metabolism and atherosclerosis.

09:02:46 22 I was the associate editor and then editor-in-chief  
09:02:48 23 of the major American Heart Association journal in this field  
09:02:53 24 that has the same acronym, ATVB, as the council because it's  
09:02:57 25 the official research publication of the council.

09:03:00 1 Then I was also selected by the American College of  
09:03:04 2 Cardiology with sponsorship from Pfizer as the visiting  
09:03:08 3 professor in preventive cardiology at the University Virginia.

09:03:11 4 Q What are professional memberships, are you a member of  
09:03:15 5 the American Heart Association or any other professional  
09:03:18 6 organization?

09:03:18 7 A Yeah, I'm fellow of the American Heart Association which  
09:03:22 8 is -- means it's a recognition of my senior standing in the  
09:03:32 9 field.

09:03:32 10 I'm a member of American University -- Association  
09:03:35 11 of University Cardiologists. I'm one of the few non chiefs of  
09:03:38 12 cardiology who was elected to that association.

09:03:41 13 I'm also a member of the American Association of  
09:03:44 14 Physicians which is an organization that has, as its members,  
09:03:52 15 people with significant accomplishments in research who are  
09:03:56 16 also physicians. So it's a group of physician scientists.

09:04:00 17 I should just point out one thing that's not on here  
09:04:03 18 because it's related to the Center for the Prevention of  
09:04:08 19 Cardiovascular disease. The Langone Medical Center, which is  
09:04:10 20 the name of our clinical center at NYU, has been ranked in the  
09:04:15 21 top ten by U.S. News World Report.

09:04:17 22 Many of you are familiar with that rating system,  
09:04:20 23 and it is a great pleasure in the last two years, that singled  
09:04:24 24 out as part of the reason for this excellence was the Center  
09:04:27 25 for the Prevention of Cardiovascular Disease.

09:04:30 1 So that's an honor I don't take as an individual,  
09:04:33 2 but I'm very proud of the accomplishments of the center, and  
09:04:37 3 it's been recognized now nationally.

09:04:39 4 Q Do you -- just to go back to the center for a moment, in  
09:04:42 5 your current position, do you still see patients?

09:04:45 6 A I do.

09:04:46 7 Q And can you explain what -- how that works for you in  
09:04:50 8 your current position.

09:04:51 9 A Okay. I should just back up and just say that from 1997,  
09:04:59 10 at Mount Sinai, to 2010 I had an office practice in preventive  
09:05:05 11 cardiology focusing on lipids.

09:05:08 12 When I went to Oxford, of course, my patients had to  
09:05:11 13 be assigned to my colleagues because I wasn't going to be in  
09:05:14 14 New York.

09:05:14 15 And when I came back -- after this sabbatical, I  
09:05:17 16 came back refreshed with ideas for expanding the center  
09:05:21 17 further which required recruiting more people, more  
09:05:25 18 fundraising, more administrative work.

09:05:27 19 So I gave up my office practice then, but because I  
09:05:30 20 had started by that time one of the few fellowships in  
09:05:35 21 preventive cardiology, I started to take my turn as what's  
09:05:39 22 called an attending physician in preventive cardiology in  
09:05:43 23 which I worked with a fellow to see patients that are coming  
09:05:47 24 through our intervention service in cardiology to give them a  
09:05:51 25 comprehensive assessment of their risk factors and suggested

09:05:55 1 treatment plan to them and their referring physician so --  
09:05:59 2 simply so we don't see them back in the hospital anytime soon.

09:06:03 3 So, I do this, I take the rotation with my  
09:06:06 4 colleagues about every five weeks. So that's about ten weeks  
09:06:11 5 a year since I returned in 2011, I see patients as a  
09:06:17 6 consultant on the inpatient service.

09:06:19 7 Q Is this the first time you've served as an expert witness  
09:06:23 8 in a patent case?

09:06:24 9 A This is the second.

09:06:26 10 Q What was the first?

09:06:26 11 A It was *Amgen versus Sanofi Regeneron* in a patent  
09:06:33 12 infringement case over antibodies for what's called PCSK9.

09:06:42 13 Q And what is PCSK9?

09:06:45 14 A This is a protein in our bodies that degrades, promotes  
09:06:52 15 the degradation of the LDL receptor. So with fewer LDL  
09:06:58 16 receptors on the surface of our cells, particularly liver  
09:07:02 17 cells, less LDL -- fewer LDL particles are taken up.

09:07:07 18 So it was reasoned from genetic studies that if you  
09:07:13 19 could inhibit the PCSK9 protein, then you would have less  
09:07:19 20 degradation or destruction of LDL receptors, there would be  
09:07:24 21 more available to take up the LDL particles and LDL  
09:07:28 22 cholesterol would go down.

09:07:30 23 And, indeed, that has been developed into a  
09:07:32 24 biological agent used by preventive cardiologists to lower LDL  
09:07:38 25 cholesterol.

09:07:38 1 Q And what was your role in the case?

09:07:40 2 A I was working with the counsel for Amgen for the  
09:07:43 3 plaintiffs on the issue of obviousness of the patent.

09:07:47 4 Q Now, do you have any financial relationship or have you  
09:07:52 5 ever had any financial relationship with either of the  
09:07:57 6 defendants aside from your work on this case?

09:07:59 7 A No.

09:07:59 8 Q Going back to your medical experience, what kinds of  
09:08:08 9 lipids -- what kind of lipid disorders have you treated over  
09:08:12 10 the years?

09:08:12 11 A Well, we've heard about the common ones. There are  
09:08:16 12 people with elevations of cholesterol, people with elevations  
09:08:20 13 of triglycerides, and, very frequently, mixed dyslipidemia  
09:08:25 14 which means they have elevations of both cholesterol and  
09:08:29 15 triglycerides.

09:08:30 16 Q And have you treated patients with very high  
09:08:34 17 triglycerides?

09:08:35 18 A Meaning 500 or more?

09:08:38 19 Q Yes.

09:08:38 20 A Yes.

09:08:38 21 Q And, by the way, if I say very high triglycerides or  
09:08:42 22 severe hypertriglyceridemia, will you understand both of those  
09:08:47 23 to mean patients over 500 milligrams per deciliter?

09:08:50 24 A I will do my best.

09:08:51 25 Q Okay. I will do my best to pronounce the words without

09:08:57 1 stumbling.

09:08:58 2 Have you seen diabetic patients with elevated  
09:09:03 3 triglycerides?

09:09:03 4 A I have.

09:09:04 5 Q Have you seen diabetic patients with severely elevated  
09:09:10 6 triglycerides over 500?

09:09:10 7 A I have.

09:09:11 8 Q And what proportion of your patients over the years have  
09:09:14 9 been diabetic patients?

09:09:16 10 A About a third.

09:09:17 11 Q And are diabetic patients particularly prone to lipid  
09:09:22 12 disorders?

09:09:22 13 A They are. They most frequently have this mixed  
09:09:26 14 dyslipidemia that I mentioned before, which in fact the  
09:09:30 15 classic they call it a triad. The classic is elevated LDL  
09:09:36 16 cholesterol, elevated triglycerides, and low HDL cholesterol.

09:09:40 17 Q And how often have you seen patients with very high  
09:09:44 18 triglycerides over the years?

09:09:45 19 A They're rare, and so I would say at least a dozen. But,  
09:09:49 20 but they are rare as we've heard.

09:09:51 21 Q And has that rare patient group that you've seen included  
09:09:57 22 diabetics with very high triglycerides?

09:09:59 23 A Yes.

09:09:59 24 MS. HUTTNER: Your Honor, we would offer  
09:10:01 25 Dr. Fisher as expert in field of preventive cardiology and the

1 investigation and treatment of lipid disorders and  
2 atherosclerosis and diabetics and other patients.

3 MR. SIPES: No objection, Your Honor.

4 THE COURT: The motion is granted.

5 BY MS. HUTTNER:

6 Q All right, sir. At the beginning of your testimony we  
7 talked about the fact that your role here is to respond to the  
8 opinions of Dr. Mason and Dr. Ismail and, to a limited extent,  
9 Dr. Toth, correct?

10 A Yes.

11 Q And it's little bit unusual here -- maybe not unusual,  
12 but we have not heard from those gentlemen yet in this case,  
13 correct?

14 A Yes.

15 Q So your testimony is in relation to the opinions that  
16 they have set forth in their expert reports?

17 A Yes.

18 Q And how did you -- let me just ask you, you've been in  
19 the courtroom since the beginning of case, correct?

20 A Yes.

21 Q And you've heard all of the prior witness testimony?

22 A I have.

23 Q How did you go about evaluating the opinions of Dr. Mason  
24 and Dr. Ismail and Dr. Toth?

25 A Well, I read -- sorry. I read their reports. I also

1 read the literature that they were citing in support of their  
2 statements, and, in some cases, went to citations within those  
3 citations that go more deeply.

4 I have extensive experience in this area, so I also  
5 used my own knowledge base and papers that I was familiar  
6 with, and then I also used materials that counsel pointed out  
7 to me.

8 Q And did you review the patents that are being asserted by  
9 Amarin in this case?

10 A I did.

11 Q And the claims of those patents?

12 A I did.

13 Q Now, in connection with your work on this case, did  
14 counsel explain to you certain legal principles that are  
15 applicable to the analysis of obviousness and objective  
16 evidence of nonobviousness?

17 A Yes.

18 Q And were you here in court when Dr. Heinecke testified  
19 about the legal standards he was told to apply in connection  
20 with his evaluation of obviousness?

21 A Yes.

22 Q And did you apply those same legal principles in  
23 connection with your work on this case?

24 A I did.

25 Q Did you also hear Dr. Heinecke testify about his

09:12:12 1 definition of the level of ordinary skill in this case?

09:12:16 2 A I did.

09:12:16 3 Q And you heard -- also heard Dr. Heinecke testify about  
09:12:20 4 Dr. Toth's definition of ordinary skill in this case?

09:12:24 5 A I did.

09:12:24 6 Q And do you agree with Dr. Heinecke's definition of  
09:12:27 7 ordinary skill?

09:12:28 8 A I do.

09:12:29 9 Q And is that the standard you applied in your analysis?

09:12:31 10 A I did.

09:12:32 11 Q What is the principle difference, as you understand it,  
09:12:36 12 between Dr. Toth's definition of ordinary skill and  
09:12:40 13 Dr. Heinecke's?

09:12:40 14 A Dr. Toth's includes nurse practitioners and physician  
09:12:45 15 assistants.

09:12:45 16 Q And do you agree that nurse practitioners and physician's  
09:12:49 17 assistants who meet the other criteria in Dr. Toth's  
09:12:51 18 definition of ordinary skill should be included?

09:12:54 19 A No. I think the issues are more sophisticated than I  
09:13:01 20 would expect people with that training to have to be able to  
09:13:05 21 evaluate.

09:13:06 22 Q Now, do you qualify as a person of ordinary skill in the  
09:13:10 23 art under either the definition that Dr. Heinecke put forth or  
09:13:14 24 Dr. Toth put forth?

09:13:15 25 A I do.

09:13:15 1 Q And does it make any difference in terms of the opinions  
09:13:18 2 that you're going to testify to whether the Court adopts  
09:13:21 3 Dr. Heinecke's definition or Dr. Toth's definition of ordinary  
09:13:28 4 skill?

09:13:28 5 A No.

09:13:28 6 Q Your opinions would be the same either way?

09:13:31 7 A Yes.

09:13:33 8 Q Okay. You mentioned that you've treated diabetic and  
09:13:38 9 nondiabetic patients with elevate triglycerides, right?

09:13:41 10 A Yes.

09:13:42 11 Q And we've heard in this case about classifications of  
09:13:44 12 elevated triglycerides, the various buckets into which they're  
09:13:48 13 decided currently under ATP III.

09:13:50 14 A Yes.

09:13:51 15 Q And you're familiar with those guidelines -- those  
09:13:54 16 classifications.

09:13:54 17 A I am.

09:13:55 18 Q And you're familiar with the ATP guidelines -- ATP III  
09:13:58 19 guidelines as well?

09:13:59 20 A Yes.

09:14:01 21 MS. HUTTNER: Can I have DX 1876, please.

09:14:05 22 And Your Honor, DX 1876 is already in evidence.

09:14:08 23 THE COURT: Thank you.

09:14:08 24 BY MS. HUTTNER:

09:14:10 25 Q Can you -- let me just ask you this. Do you have -- 1876

09:14:15 1 is a copy of the ATP III guidelines, correct?

09:14:17 2 A Yes.

09:14:17 3 Q And it's a fairly large document?

09:14:19 4 A The full -- the full version is hundreds of pages.

09:14:23 5 MS. HUTTNER: All right. Mr. Gross, can you  
09:14:24 6 pull up table II.3-1 which is entitled Classification of Serum  
09:14:32 7 Triglycerides at the top of page 25, and can you blow up that  
09:14:35 8 table, please.

09:14:35 9 BY MS. HUTTNER:

09:14:40 10 Q Okay. Table II.3-1 is entitled "Classification of Serum  
09:14:45 11 Triglycerides," and this is little bit different than the  
09:14:48 12 table that we looked at before because it includes the ATP II  
09:14:52 13 levels as well, correct?

09:14:53 14 A Yes.

09:14:53 15 Q And ATP -- am I correct in understanding that ATP II was  
09:14:57 16 the predecessor to ATP III?

09:14:59 17 A Yes.

09:15:00 18 Q And ATP III was adopted, I think we heard, around 2002?

09:15:04 19 A It was published then, but I think the first summary was  
09:15:09 20 distributed in 2001. But -- and then it was published in  
09:15:14 21 various formats and journals over the next year.

09:15:18 22 Q Now, are there differences between the boundaries for the  
09:15:22 23 different triglyceride categories between ATP II and ATP III?

09:15:28 24 A Yes, there are.

09:15:29 25 Q And under ATP II -- well, why don't you explain what the

09:15:32 1 differences are.

09:15:33 2 A Well, in ATP II, the normal range was considered to be  
09:15:37 3 less than 200. In ATP III, that was lowered to less than 150.

09:15:43 4 And I won't keep repeating the units, but they're  
09:15:46 5 all milligrams per deciliter. That means milligrams per  
09:15:51 6 hundred MLs of your blood.

09:15:53 7 The borderline high triglycerides in ATP II was 200  
09:15:58 8 to 399, whereas in ATP III, as we see, 150 to 199.

09:16:05 9 The high triglyceride group in ATP II was 400 to  
09:16:10 10 1000; in ATP III, 200 to 499.

09:16:16 11 And the very high or severely high triglyceride  
09:16:19 12 levels in ATP II were classified as greater than a thousand,  
09:16:23 13 and greater than five -- or greater than or equal to 500 in  
09:16:29 14 ATP III.

09:16:30 15 Q And do you have an understanding of why those -- the  
09:16:33 16 boundaries of those various triglyceride categories changed  
09:16:36 17 between ATP II and ATP III?

09:16:39 18 A Well, the document did make mention that by taking into  
09:16:42 19 account ongoing research, I think ATP II was 7 or 8 years  
09:16:47 20 prior to ATP III, and they reconvened these committees to  
09:16:53 21 bring in new findings.

09:16:55 22 And it was the feeling of the committee that in  
09:17:00 23 general there needed to be, in recognition of certain studies,  
09:17:05 24 a more conservative classification system so that the risk of  
09:17:13 25 both the coronary artery disease in the -- in the categories

below the very high triglycerides were adjusted to reflect some clinical studies that had been published.

And the risk of pancreatitis, that is what's most important in the treatment of very high triglycerides, we should start becoming more concerned about that risk at a lower level of triglycerides because once you get to thousand, the risk of pancreatitis, acute pancreatitis, is much higher and -- than at 500.

So to give, I think, a more conservative heads-up, so to speak, that this could be a potential problem, that was incorporated into the new classifications as well.

Q Focusing on the -- in this exhibit on the ATP III triglyceride categories?

A Yes.

Q Is the same nomenclature and the same boundaries, if you will, do those apply to diabetic patients?

A Yes, they do.

Q So there's nothing different as between diabetic patients and nondiabetic patients in terms of whether they're looked at as having high triglycerides or very high triglycerides?

A That is correct.

Q And we've heard some testimony previously about the way in which patients with very high triglycerides are typically treated.

Do doctors treat diabetic patients with very high

09:18:50 1 triglycerides the same way they treat nondiabetic patients  
09:18:54 2 with very high triglycerides?

09:18:56 3 A Yes, with one wrinkle, that they have poor glycemic  
09:19:02 4 control. That also needs to be addressed while you're trying  
09:19:05 5 to get the triglycerides down with medications.

09:19:07 6 Q And glycemic control refers to sugar management?

09:19:13 7 A Yes, sugar metabolism, yes.

09:19:14 8 Q We also heard some testimony in this case, and I think  
09:19:17 9 you mention pancreatitis as well, but is that an equally  
09:19:20 10 serious condition in diabetic patients?

09:19:23 11 A Yes, it is.

09:19:24 12 Q How do you treat diabetic patients with very high  
09:19:27 13 triglycerides to avoid the risk of pancreatitis?

09:19:30 14 A We treat them typically with -- with the fish oils or  
09:19:34 15 fibrates. Years ago we also used niacin, but that has fallen  
09:19:41 16 out of favor because it has been shown to impair the sugar  
09:19:49 17 metabolism in some diabetics.

09:19:51 18 Q Now, have you -- you mentioned, I think, fibrates and  
09:19:55 19 fish oils, correct?

09:19:55 20 A Yes.

09:19:56 21 Q And of -- fibrates, again, we've heard something about  
09:20:01 22 this already from the other witnesses, but briefly, can you  
09:20:03 23 remind us what fibrate drugs are.

09:20:05 24 A So these are small molecule drugs. We heard a little bit  
09:20:11 25 from Dr. Heinecke about some of the potential mechanisms at

09:20:16 1 the molecular level. But I think in general they're thought  
09:20:19 2 to stimulate the action of lipoprotein lipase which we have  
09:20:34 3 also heard is a key player in reducing triglyceride levels in  
09:20:35 4 blood.

09:20:35 5 So that's their principal action and why it's  
09:20:39 6 thought that they are effective in lowering triglyceride  
09:20:42 7 levels.

09:20:42 8 Q And when you refer to fish oils in your prior answer, can  
09:20:45 9 you explain what fish oils you were referring to.

09:20:48 10 A These are typically combinations, back in 2008 or before,  
09:20:59 11 of EPA and DHA.

09:21:01 12 Q And are you referring only to prescription fish oils?

09:21:04 13 A No, the over-the-counter fish oils were typically  
09:21:09 14 combinations of EPA and DHA as well.

09:21:12 15 Q And what kinds of fish oils did you prescribe or  
09:21:15 16 recommend to patients with very high triglycerides to lower  
09:21:19 17 their triglycerides?

09:21:20 18 A Well, prior to 2004, when Lovaza was approved, we would  
09:21:28 19 use the best quality as far as we can determine of fish oils  
09:21:33 20 that were available over the counter.

09:21:35 21 But I would say that our usual approach was to use  
09:21:42 22 fenofibrate, fibrates, because of their effectiveness and  
09:21:48 23 their ease of use. There was a lot of experience using  
09:21:57 24 fibrates for lowering very high triglyceride levels.

09:22:01 25 We would turn to fish oils, for example, in patients

1 who would not want to take a prescription drug. There are  
2 many patients who feel taking something from nature, more  
3 natural is better.

4 And so we sometimes would make decisions on the  
5 therapy based on patient considerations, including the  
6 occasional patients who couldn't tolerate the fibrates also.  
7 All drugs have some side effects, so that would occasionally  
8 be an issue.

9 Q Have you prescribed or recommended prescribing both  
10 Vascepa and Lovaza to diabetic patients?

11 A Yes.

12 Q And, I apologize, I think there's some controversy as to  
13 whether it's Lovaisa or Lovaza. I think it is Lovaza, I'll  
14 try to remember that.

15 Have you prescribed Lovaza -- I'm sorry, when you  
16 have prescribed Lovaza to -- well, how do you instruct  
17 patients to take Lovaza?

18 A Well, they -- it's -- the indication is 4 grams a day, so  
19 typically taking two capsules twice a day.

20 Q And when a patient comes into the center with very high  
21 triglycerides, do you write them a prescription or do you  
22 recommend lifestyle modification?

23 A Well, as we discussed, the use of drugs is also -- is  
24 always -- to lower lipids is always an adjunct to recommending  
25 lifestyle changes, and so we -- we do both.

09:23:40 1 In practice, when someone has severely high  
09:23:44 2 triglycerides, though, that you worry so much about the risk  
09:23:47 3 of the acute pancreatitis, is that you instruct them about the  
09:23:53 4 need for lifestyle changes.

09:23:55 5 But in our center, for example, we have a  
09:23:58 6 nutritionist, we have exercise physiologists, they need expert  
09:24:03 7 guidance to modify their life in ways that they understand why  
09:24:08 8 they're doing these things.

09:24:09 9 And it can take -- just like any other clinical  
09:24:12 10 center, it can take weeks or as long as a month before they  
09:24:17 11 can get an appointment with these people.

09:24:20 12 So we feel that we can't wait to withhold the drug  
09:24:23 13 when we're concerned about a volcano erupting, so to speak,  
09:24:29 14 because you can't predict when the pancreatitis attack will  
09:24:32 15 occur.

09:24:33 16 So we always recommend the lifestyle changes, but  
09:24:37 17 we'll start the prescription drug at the same time.

09:24:41 18 Q Now, did you prescribe fibrates to diabetic patients with  
09:24:47 19 very high triglycerides before 2008?

09:24:49 20 A Yes.

09:24:49 21 Q And are fibrates still used in diabetic patients to lower  
09:24:55 22 triglycerides?

09:24:55 23 A They are.

09:24:56 24 MS. HUTTNER: Can I have DDX 9.8, please.

09:24:56 25

09:24:56 1 BY MS. HUTTNER:

09:25:05 2 Q DDX 9.8 is a blowup of paragraph 29 from Dr. Ismail's  
09:25:12 3 expert report. Do you recall this paragraph?

09:25:15 4 A Yes.

09:25:15 5 Q And in this paragraph, Dr. Ismail says that fibrates are  
09:25:19 6 bad because they can cause an increase in LDL-C in diabetic  
09:25:23 7 patients, and I think we've heard that from some of the  
09:25:26 8 witnesses here as well. Do you recall that?

09:25:27 9 A Yes.

09:25:28 10 Q Does the ADA recommend the use of fibrates in diabetic  
09:25:34 11 patients with very high triglycerides?

09:25:36 12 A They do.

09:25:38 13 MS. HUTTNER: Can I have DDX 9.128, please.

09:25:38 14 BY MS. HUTTNER:

09:25:41 15 Q Can you identify DX 2124 which is in the background here.

09:25:48 16 A Yes. That is a publication in the *Journal of Diabetes*  
09:25:55 17 *Care* which includes the current standards of care, medical  
09:26:02 18 care for people with diabetes.

09:26:06 19 That is put together by the American Diabetes  
09:26:10 20 Association, and I believe the date that is covered up partly  
09:26:13 21 is 2019 so this is their most recent iteration of these  
09:26:18 22 guidelines.

09:26:19 23 Q And is DX 2124 one of the documents that you considered  
09:26:22 24 in connection with your opinions in this case?

09:26:24 25 A I did.

09:26:24 1 Q And it's discussed and disclosed in your expert report?

09:26:28 2 A Yes.

09:26:29 3 MS. HUTTNER: Your Honor, we would move DX 2124  
09:26:31 4 into evidence.

09:26:32 5 MR. SIPES: No objection, Your Honor.

09:26:32 6 THE COURT: 2124 is admitted.

09:26:32 7 (Plaintiff's Exhibit 2124 received in  
09:26:32 evidence.)

09:26:32 8 BY MS. HUTTNER:

09:26:36 9 Q Now, on DDX 9.128, there is a snapshot of an excerpt  
09:26:42 10 that's on page 120 of DX 2124. Can you explain what is shown  
09:26:47 11 here.

09:26:47 12 A Yes, this is just highlighting the recommendations with  
09:26:53 13 people, diabetics who have severe hypertriglyceridemia defined  
09:26:58 14 as fasting triglycerides equal or greater than 500, and they  
09:27:05 15 may warrant pharmacologic therapy, and they mention two  
09:27:08 16 agents, specifically fibric acid derivatives and/or fish oil,  
09:27:14 17 to reduce the risk of acute pancreatitis.

09:27:16 18 Q And is fibric acid derivatives, that's the same as  
09:27:21 19 fibrates?

09:27:21 20 A Yes.

09:27:22 21 Q And the fish oil that's referred to here, does the ADA  
09:27:25 22 with respect to diabetics with very high triglycerides, do  
09:27:29 23 they have a recommendation one way or the other as between  
09:27:32 24 Lovaza and Vascepa?

09:27:33 25 A No.

09:27:33 1 Q Now, we've heard some testimony as I mentioned about  
09:27:42 2 fibrates raising LDL-C, correct?

09:27:45 3 A Yes.

09:27:45 4 Q And you heard that testimony as well.

09:27:48 5 A I did.

09:27:48 6 Q Does every diabetic patient with very high triglycerides  
09:27:53 7 experience an increase in LDL-C when they take a fibrate?

09:27:57 8 A Every single one, no. On average, yes, but not every  
09:28:02 9 single one.

09:28:02 10 Q So we've also heard I think from a number of witnesses  
09:28:05 11 that an increase in LDL-C is considered an indication of an  
09:28:09 12 increased risk of heart disease. Is that your understanding  
09:28:12 13 as well?

09:28:12 14 A Yes. But in the context of severely high triglycerides,  
09:28:19 15 the treatment goal is the -- reducing the risk of acute  
09:28:24 16 pancreatitis, and the cardiovascular risk is not of concern in  
09:28:30 17 that setting.

09:28:30 18 Q Is that true with respect to diabetic patients who are at  
09:28:36 19 an increased risk of heart disease?

09:28:38 20 A It's independent of that.

09:28:40 21 Q So in diabetic patients is the treatment goal any  
09:28:43 22 different for patients with very high triglycerides than it is  
09:28:48 23 in nondiabetic patients?

09:28:50 24 A No, it's same goal to reduce the risk of acute  
09:28:54 25 pancreatitis.

09:28:54 1 Q Now, why is it that the ADA is not concerned in the case  
09:28:59 2 of patients with very high triglycerides about giving them a  
09:29:02 3 medication that can increase their LDL?

09:29:05 4 A Well, the one thing that's not mentioned here is that the  
09:29:09 5 standard of care since the heart protection study in 2002 or  
09:29:14 6 so, the standard of care is that independent of a diabetic's  
09:29:19 7 LDL cholesterol levels, they should all be on at least a  
09:29:23 8 moderate-intensity statin.

09:29:25 9 And when a patient is on a moderate-intensity statin  
09:29:29 10 or high-intensity statin, the increase in LDL cholesterol is  
09:29:36 11 not of concern because the statin is lowering the levels of  
09:29:40 12 LDL cholesterol because of the way statins work.

09:29:42 13 Q Now, do you attend any medical meetings?

09:29:45 14 A I do.

09:29:45 15 Q How often do you attend them?

09:29:47 16 A I go to two or three a year.

09:29:49 17 Q And how long have you been doing that?

09:29:50 18 A A long time; at least 20 years.

09:29:53 19 Q And at any of these meetings prior to 2008, did you ever  
09:29:58 20 hear anyone raise a concern about giving fibrates to diabetic  
09:30:03 21 patients with very high triglycerides because of the  
09:30:05 22 possibility that the drug would increase their LDL-C level?

09:30:09 23 A I don't recall that.

09:30:10 24 Q And in your practice, have you ever seen an increase in  
09:30:15 25 LDL-C in a severely hypertriglyceridemic diabetic patient that

09:30:21 1 you have given a fibrate drug to?

09:30:23 2 A I'm not -- could you repeat that?

09:30:26 3 Q Yeah, in your own practice, have you ever seen a  
09:30:31 4 clinically concerning rise in LDL-C in a diabetic patient with  
09:30:37 5 severe triglyceridemia that you've treated with fibrate drugs?

09:30:43 6 A No, because we have them on statins.

09:30:45 7 MS. HUTTNER: Now, if we can go back to DDX 9.8,  
09:30:49 8 please.

09:30:49 9 BY MS. HUTTNER:

09:30:51 10 Q This is, again, the slide that we looked at earlier from  
09:30:56 11 Dr. Ismail's corrected opening expert report. This is  
09:31:00 12 paragraph 29, and in this paragraph Dr. Ismail claims that  
09:31:06 13 fibrates are disfavored because they increase the risk of  
09:31:10 14 muscle breakdown. Do you see that there?

09:31:12 15 A Yes, I do.

09:31:13 16 Q And do you agree with that statement?

09:31:15 17 A In part. The particular fibrate that had that problem,  
09:31:23 18 or has that problem is gemfibrozil which is noted earlier in  
09:31:28 19 this paragraph as the prescription drug Lopid, L-o-p-i-d.

09:31:36 20 That was a form of a fibrate that was known to have  
09:31:42 21 this complication of increased risk of rhabdomyolysis  
09:31:49 22 particularly when used in combination with statins, but  
09:31:53 23 particularly with one specific statin as I think he notes  
09:31:58 24 here, cerivastatin. Actually, I don't see if it's there.  
09:32:12 25 Cerivastatin is c-e-r-i-v-a-s-t-a-t-i-n.

09:32:12 1 That statin was withdrawn from the market and, with  
09:32:15 2 the fenofibrates also being available, Tricor is one that's  
09:32:21 3 mentioned here, that without the same increased risk the  
09:32:26 4 overwhelming use of fibrates has become fenofibrates.

09:32:32 5 And the last data that I saw on the percentage of  
09:32:39 6 patients who were on the combination of a statin with a  
09:32:43 7 fenofibrate that had rhabdomyolysis was about 0.12 percent  
09:32:51 8 which I don't think is materially different from the rate that  
09:32:55 9 you get with some statins alone. So the rate is very -- is  
09:33:01 10 very low.

09:33:02 11 Q He also mentions, Dr. Ismail, in paragraph 29, what he  
09:33:06 12 calls other safety concerns related to the use of fibrates,  
09:33:11 13 and he mentions hepatotoxicity, decline in renal function,  
09:33:18 14 dyspepsia, gastrointestinal complaints, and gallstones. Do  
09:33:22 15 you so see that?

09:33:24 16 A I do.

09:33:24 17 Q Do those concerns have anything to do or did they  
09:33:26 18 influence your decision whether or not to prescribe a fibrate  
09:33:30 19 drug to a patient with very high triglycerides?

09:33:33 20 A No, these are all at very low percentages.

09:33:36 21 If any of you has been brave enough to read the full  
09:33:39 22 prescribing information for anything that you're taking,  
09:33:42 23 you'll see a whole list of potential adverse events that have  
09:33:48 24 to be listed, and they are typically at very low levels.

09:33:53 25 So this has not been any impediment to me or my

colleagues from using fibrates, particularly fenofibrates.

Q Before we leave the topic of fibrates, I want to ask you about something that Dr. Budoff said during his testimony that I did not fully understand, and this is on -- this is from the day two rough transcript at pages 36 to 38, and I'm not going to read through all of it.

MS. HUTTNER: Can you blow up the highlighted portions?

THE COURT: And I want to make sure the record reflects that the rough transcript is not the official transcript.

MS. HUTTNER: Understood, Your Honor.

BY MS. HUTTNER:

Q Okay. So just for context, the discussion pertained to what Dr. Budoff was describing as the downside of fibrate drugs, and I want to direct your attention --

MS. HUTTNER: And, Mr. Gross, if you could bring up the question.

BY MS. HUTTNER:

Q "Can you characterize how often you describe" -- I think it should be prescribe "fibrates to STG patients earlier in your career compared to now."

And Dr. Budoff responded -- do we have that up there? Yeah.

He responds, and he says that,

09:35:20 1 "After 2016, the Food and Drug Administration  
09:35:23 2 opined that you cannot use a fibrate and a statin  
09:35:23 3 together. So now I can't use fibrates in most cases  
09:35:31 4 of severe hypertriglyceridemia."

09:35:34 5 And focusing on that question and answer, is it  
09:35:37 6 your understanding that the FDA has opined that you should not  
09:35:41 7 give fibrate drugs to patients on statins?

09:35:45 8 A In general, no. There was a specific consideration here.

09:35:50 9 Q Which was what?

09:35:51 10 A In my reading of that document, the FDA was not allowing  
09:35:58 11 an indication to be granted to a combination drug of a  
09:36:03 12 fenofibrate and a statin.

09:36:06 13 The company wanted an indication for the changes in  
09:36:11 14 HDL cholesterol and reduction in cardiovascular risk, and FDA  
09:36:17 15 did not think that evidence warranted such an indication.  
09:36:20 16 There was absolutely no mention in that document of any safety  
09:36:23 17 issue in using the combination.

09:36:24 18 Q And are you aware of any safety issue of using the  
09:36:28 19 combination of fibrates and statin drugs?

09:36:29 20 A No. I mean, we monitor patients like any other  
09:36:34 21 preventive cardiology section.

09:36:37 22 These patients are on a lot of medications,  
09:36:39 23 particularly the diabetics, and we do periodic blood tests to  
09:36:46 24 make sure there are no side effects or adverse actions, but  
09:36:51 25 that's just routine. They get no more than the routine

09:36:56 1 surveillance that we do with all patients.

09:36:58 2 Q Let's change topics a bit and let's talk -- if we can go  
09:37:02 3 to DDX 9.127. I want to shift focus to Lovaza.

09:37:10 4 Dr. Ismail's opening report also discusses Lovaza,  
09:37:13 5 correct?

09:37:14 6 A Yes.

09:37:14 7 Q And in paragraph 28, he says that,

09:37:19 8 "Lovaza was also known to significantly  
09:37:21 9 increase LDL-C in the severely hypertriglyceridemic  
09:37:26 10 patient populations."

09:37:27 11 And he goes on to say, "In a study reported  
09:37:30 12 in the Lovaza label, the increase in LDL-C as shown  
09:37:33 13 to be 49.3 percent compared with placebo."

09:37:37 14 And we've heard testimony from other witnesses  
09:37:39 15 in this court that Lovaza can raise LDL-C in some patients  
09:37:43 16 with very high triglycerides; is that right?

09:37:45 17 A Yes.

09:37:45 18 Q Now, Dr. Ismail in paragraph 28 goes on to say that, that  
09:37:52 19 the rise -- that this rise in LDL-C or potential rise with  
09:37:57 20 Lovaza is clinically concerning. Do you agree with that?

09:38:01 21 A No, I do not.

09:38:03 22 Q Can you explain why.

09:38:05 23 A Well, again, the -- in the short-term what you really  
09:38:09 24 want to avoid is pancreatitis, and that is the indication for  
09:38:14 25 using Lovaza in severely high hypertriglyceridemic patients to

get the triglycerides levels below 500.

Again, in the -- in the diabetic population in particular, they are on statins already which will also be protective against LDL cholesterol.

The general pattern is that the cardiovascular risk of the LDL only becomes a factor in the treatment plan after you have gotten out of the dangerous situation of bringing the triglycerides down. So it's not -- it's not a consideration.

Q Has the fact that Lovaza can raise LDL-C in some patients with very high triglycerides particularly diabetic patients, has that deterred you in any way from prescribing Lovaza to diabetic patients with very high triglycerides?

A No.

Q Prior to -- I'm sorry, prior to 2008, did you ever hear anyone in the medical community express concerns or publish an article in which they expressed concerns about giving Lovaza to diabetic patients with very high triglycerides because of the possibility that that their LDL-C would go up?

A No. Again, I think in part -- in large part because standard of care was to have all those patients on statins.

Q And has there been -- to your knowledge, has the ADA issued any cautions about using Lovaza in diabetic patients?

A No, we saw in the 2019 guidelines that they just say fish oils.

Q Okay. Let's move on to Dr. Ismail's opinions about

09:40:06 1 alleged objective evidence of nonobviousness in this case.

09:40:09 2 MS. HUTTNER: And if we can go to DDX 9.13.

09:40:09 3 BY MS. HUTTNER:

09:40:13 4 Q This is -- DDX 9.13 is from the corrected opening report  
09:40:20 5 of Dr. Ismail, specifically paragraph 7. Does this paragraph  
09:40:26 6 summarize Dr. Ismail's opinions at least as he articulated  
09:40:31 7 them in his report?

09:40:32 8 A Yes, it does.

09:40:33 9 Q And the call-out on DDX 9.13 has three bullets, correct?

09:40:39 10 A Yes.

09:40:40 11 Q And is it your understanding that these represent the  
09:40:43 12 opinions that Dr. Ismail plans to testify about in court?

09:40:47 13 A That's my understanding.

09:40:48 14 Q All right. The first opinion in paragraph 7 is that  
09:40:52 15 Vascepa met a long-felt but unmet need for method of treating  
09:40:57 16 diabetic patients with very high triglycerides without causing  
09:41:00 17 serious side effects or an increase in the patient's so-called  
09:41:04 18 bad cholesterol or LDL-C and also decreasing apo B.

09:41:10 19 Is it that your understanding -- is it your  
09:41:12 20 understanding Dr. Ismail has that opinion?

09:41:14 21 A Yes, it's my understanding.

09:41:15 22 Q And the next two opinions, the second opinion is -- in  
09:41:19 23 Dr. Ismail's report is that Vascepa met a long-felt but unmet  
09:41:25 24 need for a treatment that would lower cardiovascular risk in  
09:41:28 25 the diabetic patient population. Is that your understanding

09:41:31 1 as well?

09:41:32 2 A Yes.

09:41:32 3 Q And he also adds that others had failed, in his opinion,  
09:41:36 4 to develop a triglyceride-lowering treatment that also reduced  
09:41:42 5 cardiovascular, correct?

09:41:42 6 A Yes.

09:41:43 7 Q And Dr. Ismail's last opinion is that Vascepa  
09:41:46 8 unexpectedly lowers cardiovascular risk in diabetic patients,  
09:41:50 9 correct?

09:41:50 10 A Yes.

09:41:51 11 Q All right. So let's talk about each of those in turn.  
09:41:55 12 And let's focus first on Dr. Ismail's first opinion that  
09:41:59 13 Vascepa met a long-felt but unmet need for method of treating  
09:42:04 14 diabetic patients with -- that would not increase LDL-C and  
09:42:08 15 would lower apo B.

09:42:11 16 First of all, are you aware -- well, first of all,  
09:42:13 17 do you agree with that opinion?

09:42:14 18 A No, I don't.

09:42:16 19 Q Are you aware of any evidence before 2008 that supports  
09:42:20 20 Dr. Ismail's claim that there was such a long-felt but unmet  
09:42:24 21 need?

09:42:24 22 A No, and I don't believe he cited evidence for that.

09:42:27 23 Q And did you point that out in your responsive report in  
09:42:31 24 this case?

09:42:31 25 A I did.

09:42:32 1 Q And in paragraph -- and you pointed out what -- what did  
09:42:37 2 you point out?

09:42:37 3 A There was no citation that was given to support that  
09:42:40 4 statement.

09:42:41 5 Q And in -- did Dr. Ismail submit a reply report in this  
09:42:46 6 case?

09:42:46 7 A He did.

09:42:46 8 Q And in that reply report did Dr. Ismail cite to any  
09:42:51 9 support for his opinion about long-felt need?

09:42:53 10 A Yes, he cited an article.

09:42:55 11 MS. HUTTNER: And can I have DX 1624, please.

09:42:55 12 BY MS. HUTTNER:

09:43:06 13 Q Can you identify DX 1624.

09:43:08 14 A Yes. This is the article that was cited by Dr. Ismail.

09:43:13 15 Q In his reply report.

09:43:15 16 A In his reply report.

09:43:17 17 Q And what is the date of this article?

09:43:18 18 A 2016.

09:43:20 19 Q And this article is called the Tajuddin article; is that  
09:43:25 20 correct?

09:43:25 21 A Yes.

09:43:25 22 Q And you reviewed that article?

09:43:27 23 A I did.

09:43:28 24 MS. HUTTNER: Your Honor, we would move DX 1624  
09:43:31 25 into evidence.

09:43:32 1 MR. SIPES: No objection, Your Honor.

09:43:32 2 THE COURT: 1624 is admitted.

09:43:32 3 (Defendant's Exhibit 1624 received in  
09:43:32 evidence.)

09:43:37 4 MS. HUTTNER: Now, if we can go to DDX 9.10,  
09:43:37 5 please.

09:43:37 6 BY MS. HUTTNER:

09:43:41 7 Q DDX 9.10 is a -- from page -- the snapshot is from page 7  
09:43:48 8 of the Tajuddin article. It says it's important to avoid  
09:43:54 9 compromising LDL-C treatment goals particularly in these  
09:43:58 10 patients?

09:43:58 11 First, let me ask you, when the article says these  
09:44:01 12 patients, do you have an understanding of what patients are  
09:44:05 13 being referred to?

09:44:06 14 A Not always. One of the problem I had in following this  
09:44:09 15 article is the lumping together in some cases the high  
09:44:12 16 triglycerides with very high triglycerides and it was  
09:44:17 17 confusing in a number of places on that point.

09:44:21 18 Q And is it your understanding -- I may have asked you  
09:44:23 19 this, if I did I apologize, but is it your understanding that  
09:44:26 20 this snippet that you have at the slide here is what  
09:44:32 21 Dr. Ismail is relying on in the Tajuddin article?

09:44:36 22 A Yes.

09:44:36 23 Q The snippet goes on to say,

09:44:39 24 "The EPA-only formulation offers an option  
09:44:47 25 that is effective but does not complicate management.

09:44:47 1 While products containing both EPA and DHA may raise  
09:44:51 2 LDL-C, the EPA-only product, icosapent ethyl, does  
09:44:56 3 not."

09:45:01 4 To your understanding, did Amarin have anything  
09:45:03 5 to do with writing -- getting this article published the  
09:45:09 6 Tajuddin article?

09:45:10 7 A They had deep involvement in this article, it's creation  
09:45:14 8 and publication.

09:45:15 9 MS. HUTTNER: Can we go to DDX 9.88.

09:45:15 10 BY MS. HUTTNER:

09:45:19 11 Q Again, this is an excerpt from the Tajuddin article from  
09:45:24 12 page 8?

09:45:24 13 A Yes.

09:45:25 14 Q And what is shown here?

09:45:26 15 A Shown in the acknowledgements and disclosures are some of  
09:45:30 16 the influences of Amarin. The medical writing itself,  
09:45:35 17 assistance was provided by a company that they frequently use  
09:45:39 18 for editorial assistance to authors.

09:45:45 19 There are inputs into the editorial content by an  
09:45:50 20 employee of Amarin, Joy Bronson, as well as some input from  
09:45:57 21 one of their consultants, a Dr. Chowdhury, C-h-o-w-d-h-u-r-y.

09:46:05 22 And in the disclosures, one the authors, Amir  
09:46:10 23 Hassan, is shown to have received grant research support from  
09:46:15 24 the company and, furthermore, is a shareholder, holds stock in  
09:46:21 25 Amarin.

09:46:26 1 MS. HUTTNER: We can take that down, Mr. Gross.

09:46:26 2 BY MS. HUTTNER:

09:46:28 3 Q Do you consider the Tajuddin article to be an  
09:46:31 4 authoritative source?

09:46:33 5 A No. It comes, frankly, across more as a promotional  
09:46:37 6 piece on behalf of Amarin.

09:46:39 7 The table of studies that are shown are not  
09:46:45 8 discussed I think fairly in the text, and, again, the text  
09:46:50 9 frequently conflates the categories of high triglycerides and  
09:46:55 10 very high triglycerides in that patient population.

09:46:58 11 Q Okay. Now, Vascepa was approved, I think we've heard, in  
09:47:03 12 2012; is that correct?

09:47:04 13 A Yes.

09:47:05 14 Q And it began to be sold, I think, in 2013, correct?

09:47:09 15 A Yes.

09:47:09 16 Q And is Vascepa any better than Lovaza or fibrates at  
09:47:14 17 lowering triglycerides in diabetic patients with very high  
09:47:19 18 triglycerides?

09:47:19 19 A No.

09:47:20 20 Q Are there any differences between those?

09:47:22 21 A No, they're all pretty equivalent in that regard.

09:47:26 22 Q And when Vascepa was approved, did the fact that Vascepa  
09:47:34 23 does not affect LDL-C levels, did that play any role in your  
09:47:39 24 decision whether or not to -- you know, whether to pick Lovaza  
09:47:42 25 or Vascepa or fibrates to give to reduced triglycerides in

09:47:47 1 severely hypertriglyceridemic diabetic patients?

09:47:51 2 A No.

09:47:52 3 Q And after Vascepa was approved, did you switch any of  
09:47:58 4 your diabetic patients with very high triglycerides from  
09:48:01 5 Lovaza to Vascepa?

09:48:03 6 A No, I did not.

09:48:04 7 Q What about new patients, did you preferentially recommend  
09:48:09 8 or prescribe Vascepa over Lovaza in diabetic patients with  
09:48:15 9 very high triglycerides?

09:48:15 10 A Well, I would say I continued to probably use more often  
09:48:22 11 fenofibrate, and then concerning the fish oil preparations, as  
09:48:27 12 you know, as has been mentioned, that Lovaza became generic in  
09:48:33 13 2015. So that cost consideration for some patients was quite  
09:48:40 14 significant.

09:48:40 15 So, depending on the context that when I did use  
09:48:47 16 fish oils, a consideration was to cost as well as my previous  
09:48:54 17 experience. If I had good success with Lovaza in the past,  
09:48:57 18 and I didn't feel that it was automatically necessary for me  
09:49:03 19 to switch to Vascepa.

09:49:05 20 Q And what about after the REDUCE-IT study results came out  
09:49:09 21 in November 2019, has that had an impact on which drugs you  
09:49:13 22 prescribe to diabetic patients with very high triglycerides?

09:49:17 23 A With very high triglycerides, no.

09:49:19 24 Q And why is that?

09:49:20 25 A Well, because the goal is to get the triglycerides down

09:49:25 1 below 500, and the LDL cholesterol is just not part of that  
09:49:30 2 consideration, as, again, the ADA, the most authoritative body  
09:49:34 3 recommending treatment to diabetics is neutral on the -- or  
09:49:40 4 agnostic, whatever, on which fish oil preparation to use in  
09:49:47 5 that patient population.

09:49:49 6 It's different in the high triglyceride category  
09:49:52 7 because that is a different focus than the severely  
09:49:59 8 triglyceridemic patient.

09:50:00 9 Q What is the focus in the high triglyceride category?

09:50:04 10 A It's reduction of cardiovascular risk and having a paper  
09:50:07 11 in the *New England Journal* that shows there's a reduction in  
09:50:11 12 cardiovascular risk.

09:50:14 13 And people with lower levels of triglycerides --  
09:50:16 14 we're in the age of evidence-based medicine so that it does  
09:50:20 15 influence, can influence prescribing habits when you have a  
09:50:23 16 study that is demonstrated to show a decrease in  
09:50:28 17 cardiovascular risk in the type of patients you're seeing in  
09:50:32 18 your office.

09:50:33 19 Q Now, let's switch gears and talk about apo B, which I  
09:50:37 20 think we've heard less about in this case than LDL-C.

09:50:41 21 Apo-B is a type of lipoprotein; is that correct?

09:50:46 22 A Actually, Dr. Budoff I think used that term, it's an  
09:50:49 23 apolipoprotein. A lipoprotein is the combination of the  
09:50:56 24 protein and the lipo which is the lipid.

09:50:57 25 When it -- when the protein component is not

09:50:59 1 associated with the particle, it's an apo. Apo just means  
09:51:04 2 there's something missing. It's an apolipoprotein, so it's an  
09:51:09 3 incomplete particle.

09:51:10 4 But not to get too technical, but I've been  
09:51:14 5 studying, apo-B for about 30 years so I'm particular about its  
09:51:20 6 nomenclature.

09:51:21 7 Q Is apo B -- just very briefly, what does apo B do? What  
09:51:26 8 is its function?

09:51:28 9 A Well, it is required to -- in the liver and also in our  
09:51:34 10 intestine to form the triglyceride-rich lipoprotein. So it's  
09:51:39 11 bit of a scaffold. It's a protein that has many extended  
09:51:44 12 parts to it that like to have lipids stick to it, and this is  
09:51:49 13 called hydrophobic interactions.

09:51:53 14 And so as the apo B protein is made in our cell,  
09:51:58 15 it's like flypaper, lipids start getting stuck to it, and at  
09:52:03 16 the end of this process, you now have this ball-like structure  
09:52:08 17 that has the triglycerides and cholesterol that are on the  
09:52:13 18 VLDL particle when the particle is made in the liver, in the  
09:52:18 19 intestine, from the fats that we eat that are absorbed. They  
09:52:23 20 are packaged into the related particles, but they're called  
09:52:26 21 chylomicrons. I believe Dr. Heinecke mentioned chylomicrons,  
09:52:30 22 c-h-y-l-o-m-i-c-r-o-n-s.

09:52:36 23 Q Dr. Budoff testified that I think he said he does not  
09:52:41 24 typically measure apo B in his hypertriglyceridemic patients.  
09:52:47 25 Is that consistent with your own practice?

09:52:49 1 A Yes.

09:52:50 2 Q And is the practice any different when you see diabetic  
09:52:54 3 patients with very high triglycerides?

09:52:56 4 A No, in their initial visit and evaluation, we do not  
09:53:01 5 measure apo B in diabetics.

09:53:04 6 Q And why is that?

09:53:08 7 A Well, the standard lipid panel that's been used for years  
09:53:13 8 and continues to be used is total cholesterol, total  
09:53:18 9 triglycerides, HDL cholesterol, LDL cholesterol.

09:53:23 10 Apo B has some role in what we call advanced lipid  
09:53:28 11 testing if there are some unusual features that the patient  
09:53:33 12 has clinically or in the laboratory going forward.

09:53:38 13 So we assume with the initial evaluation and  
09:53:44 14 treatment plan for a patient that they will be more or less  
09:53:47 15 like the other patients.

09:53:48 16 But, occasionally, there's reason to suspect that  
09:53:53 17 the dose of drug we're using is not enough or there are some  
09:54:00 18 unusual properties of their lipoprotein particles and there  
09:54:03 19 are number of -- what are called advanced lipid testing that's  
09:54:08 20 used in that group down the line.

09:54:11 21 MS. HUTTNER: Now, if we could go to DDX 9.11  
09:54:15 22 please.

09:54:15 23 BY MS. HUTTNER:

09:54:16 24 Q This is again an excerpt from Dr. Ismail's opening  
09:54:19 25 report, paragraph 26. And he says that,

09:54:23 1 "In the 2009 Standards of Medical Care in  
09:54:28 2 Diabetes, the authors explained 'a consensus panel  
09:54:31 3 convened by ADA and the American College of  
09:54:35 4 Cardiology recommended a greater focus on non-HDL  
09:54:38 5 cholesterol and apolipoprotein B in patients who are  
09:54:43 6 likely to have small LDL particles. Such as people  
09:54:47 7 with diabetes.'"

09:54:49 8 The recommendation of the consensus panel that  
09:54:53 9 Dr. Ismail discusses in paragraph 26, to your knowledge, has  
09:54:56 10 that ever been adopted by either the American College of  
09:55:00 11 Cardiology or the American Diabetic Association?

09:55:03 12 A No. As an official treatment goal, no.

09:55:06 13 Q And are you aware of anyone in your field who said or  
09:55:14 14 wrote prior to 2008 that there was a long-felt need for a  
09:55:18 15 triglyceride-lowering medication in diabetic patients with  
09:55:21 16 severe hypertriglyceridemia that would reduce apo B?

09:55:26 17 A No, not to my knowledge.

09:55:28 18 Q Can I have -- well, have you prepared a slide summarizing  
09:55:32 19 the reasons why you disagreed with Dr. Ismail's opinion about  
09:55:37 20 an alleged long-felt need for a triglyceride-lowering drug  
09:55:41 21 that would not affect LDL-C and would lower apo B?

09:55:46 22 A I have.

09:55:47 23 MS. HUTTNER: Can I have DX 9.12, please.

09:55:47 24 BY MS. HUTTNER:

09:55:50 25 Q Is this the slide that you prepared?

09:55:52 1 A It is.

09:55:52 2 Q Can you just summarize, walk us through the bullets of  
09:55:56 3 this slide, please.

09:55:57 4 A Yes, on the top is the statement that in diabetic  
09:56:02 5 patients with triglycerides equal or greater than 500, the  
09:56:07 6 primary goal is to lower triglycerides to reduce the risk of  
09:56:11 7 pancreatitis.

09:56:13 8 And the standard of care for diabetic patients is  
09:56:17 9 statin therapy, regardless of LDL cholesterol levels,  
09:56:21 10 therefore increases in LDL cholesterol are not clinically  
09:56:26 11 concerning especially as compared to the risk of pancreatitis.

09:56:30 12 And the third is apo B is not typically monitored  
09:56:34 13 and is not a target for therapy in diabetic patients with very  
09:56:39 14 high triglycerides.

09:56:39 15 MS. HUTTNER: Okay. Let's move on to  
09:56:41 16 Dr. Ismail's other opinions. If we can, Mr. Gross, take us  
09:56:44 17 back to DDX 9.14.

09:56:44 18 BY MS. HUTTNER:

09:56:46 19 Q This is, again, the same summary slide from paragraph 7  
09:56:49 20 of Dr. Ismail's opening report that we looked at earlier.

09:56:52 21 We've talked about Dr. Ismail's first opinion, and I  
09:56:56 22 would like to now talk about Dr. Ismail's opinions about  
09:57:03 23 Vascepa being an unmet need for a treatment that would lower  
09:57:06 24 cardiovascular risk and stating that it was unexpected that  
09:57:10 25 Vascepa would do so.

09:57:12 1 And I want to, I guess, take those in reverse order.  
09:57:16 2 Let's start with the third bullet point in paragraph 7, which  
09:57:20 3 is Dr. Ismail's opinion that Vascepa unexpectedly lowers  
09:57:25 4 cardiovascular risk in diabetic patients a result that  
09:57:30 5 numerous other treatments have failed to produce.

09:57:32 6 First of all, do you agree with Dr. Ismail it was  
09:57:35 7 unexpected in 2008 that Vascepa would lower cardiovascular  
09:57:39 8 risk in diabetic patients?

09:57:41 9 A I do not agree.

09:57:42 10 Q All right. Let me show you DX 1553, please.

09:57:53 11 DX 1553 which is in evidence is the Yokoyama paper  
09:57:57 12 that we've -- I think we've heard about from other witnesses  
09:58:00 13 in this proceeding, and you've read this article as well,  
09:58:03 14 correct?

09:58:03 15 A Yes, I have.

09:58:04 16 Q And does this article, Yokoyama, discuss the results of  
09:58:06 17 the JELIS study?

09:58:08 18 A It does.

09:58:08 19 Q Do you rely on this article in connection with your  
09:58:15 20 opinion that there was -- that it was not unexpected that  
09:58:19 21 Vascepa would lower cardiovascular risk in diabetic patients?

09:58:22 22 A I do.

09:58:23 23 Q And specifically what do you rely on here in this  
09:58:33 24 document?

09:58:33 25 A Well, this showed that highly-purified EPA reduced the

09:58:42 1 risk of major cardiovascular events in a population of  
09:58:50 2 patients that included diabetic patients.

09:58:55 3 Q And in paragraph 40 of Dr. Ismail's opening report,  
09:59:02 4 Dr. Ismail commented that the JELIS study did not show a  
09:59:10 5 statistically significant cardiac risk reduction in the  
09:59:13 6 diabetic patients enrolled in that study.

09:59:20 7 On the slide that's up now is DDX 9.115, this is an  
09:59:25 8 excerpt from paragraph 40 of Dr. Ismail's opening expert  
09:59:32 9 report.

09:59:32 10 And Dr. Ismail says there that the JELIS study was  
09:59:35 11 unable to establish a statistically significant reduction in  
09:59:39 12 the risk of major coronary events in a subanalysis of the  
09:59:43 13 Japanese hypercholesterolemic patient population with  
09:59:47 14 diabetes, and then he lists in parentheses both the hazard  
09:59:53 15 ratio and the confidence interval relating to that ratio.

09:59:56 16 Do you recall this statement in Dr. Ismail's report?

09:59:58 17 A I do.

09:59:59 18 Q And let me direct you to Table 2 from the Yokoyama  
10:00:05 19 article, which I think we have in DDX 9.16, please.

10:00:09 20 And just to orient ourselves, the hazard ratio  
10:00:15 21 referred in Dr. Ismail's report is highlighted for diabetic  
10:00:21 22 patients in this slide, correct?

10:00:22 23 A Yes.

10:00:23 24 Q And absent means they don't have diabetes, and present  
10:00:26 25 means they do, correct?

10:00:28 1 A Yes, as a physician diagnosis criteria.

10:00:33 2 Q So if I look at the hazard ratio for diabetic patients.  
10:00:37 3 It goes from 0.65 to 1.15, correct?

10:00:42 4 A Yes.

10:00:42 5 Q And the fact that it goes above 1 means that it's not  
10:00:46 6 statically significant as to that particular cohort?

10:00:50 7 A That is correct.

10:00:52 8 Q There's another value in Table 2 called interaction P.

10:00:56 9 A Yes.

10:00:57 10 Q Can you explain what that means.

10:00:59 11 A An interaction test is typically used to see whether a  
10:01:06 12 condition or a factor that a patient would have would  
10:01:12 13 interfere or influence the effect of the treatment.

10:01:17 14 So in this case, what the interaction was testing is  
10:01:24 15 whether or not EPA would have a different effect in the  
10:01:27 16 patients in the population, the study population who had or  
10:01:31 17 did not have diabetes.

10:01:34 18 So the interaction being nonsignificant, that .62 is  
10:01:40 19 not significant, means that the effects of EPA were equivalent  
10:01:45 20 in the patients with diabetes or without. In other words,  
10:01:50 21 cannot distinguish one group from the other in terms of the  
10:01:54 22 effect of EPA.

10:01:55 23 Q And based on the interaction P value, would you expect  
10:01:59 24 that diabetics would get the same benefit from EPA as  
10:02:04 25 nondiabetic patients?

10:02:05 1 MR. SIPES: Objection, Your Honor. None of this  
10:02:07 2 is in his report.

10:02:07 3 THE COURT: Ms. Huttner?

10:02:09 4 MR. SIPES: There's no discussion of interaction  
10:02:11 5 P values.

10:02:12 6 MS. HUTTNER: Your Honor --

10:02:12 7 THE COURT: The objection is the testimony here  
10:02:14 8 exceeds the scope of his report.

10:02:15 9 MR. SIPES: Correct.

10:02:17 10 MS. HUTTNER: Dr. Fisher does discuss the  
10:02:20 11 Yokoyama disclosure with respect to diabetic patients in his  
10:02:23 12 report, and he also discusses the reference in response to  
10:02:27 13 Dr. Ismail's opinions that the results in Yokoyama are not  
10:02:31 14 statistically significant.

10:02:34 15 This is Table 2 from the Yokoyama article which  
10:02:36 16 is part of what informed Dr. Fisher's opinions.

10:02:39 17 THE COURT: Do you have the excerpts from  
10:02:42 18 Dr. Fisher's report that you're relying on?

10:02:45 19 MS. HUTTNER: I do.

10:02:48 20 Can I have a copy of Dr. Fisher's report.

10:03:26 21 May I approach, Your Honor?

10:03:27 22 THE COURT: Yes.

10:03:29 23 MS. HUTTNER: It's paragraph 126, Your Honor.

10:03:33 24 THE COURT: Twenty-six?

10:03:34 25 MS. HUTTNER: 126. Actually, it starts at

10:03:43 1 paragraph 125, so it's 125 and 126, and it continues on. This  
10:03:50 2 topic continues on through, I believe, 127.

10:03:58 3 MR. SIPES: And, Your Honor, one thing I would  
10:04:00 4 note to inform your reading, 126 which refers to the Sato  
10:04:05 5 paper I believe is a different later paper that was not  
10:04:07 6 identified for use today by defendants.

10:04:11 7 MS. HUTTNER: It's on our exhibit list.

10:04:13 8 MR. SIPES: It is not on the list of exhibits  
10:04:15 9 you identified for use today with Dr. Fisher, the Saito paper.

10:04:15 10 MS. HUTTNER: I don't believe -- well, I don't  
10:04:21 11 want to argue with you, but the disclosures were of the  
10:04:23 12 demonstratives that we planned to use.

10:04:26 13 MR. SIPES: And you can see that, Your Honor,  
10:04:28 14 because --

10:04:28 15 THE COURT: Would you give me a moment to read  
10:04:30 16 it.

10:04:30 17 MR. SIPES: Sure.

10:04:31 18 THE COURT: Then you can tell me what is missing  
10:04:33 19 here, Mr. Sipes.

10:04:34 20 MR. SIPES: Yes.

10:05:22 21 THE COURT: (Court reviews the document.)

10:05:24 22 All right. So, Mr. Sipes, what do you want me  
10:05:26 23 to know?

10:05:27 24 MR. SIPES: Couple of things. The two  
10:05:29 25 paragraphs that are identified in 125 and 126 is discussing a

1 different paper, that you can see at the end of paragraph 125,  
2 it's citing Saito 2008. That is not the Yokoyama 2007 paper,  
3 and it was -- the Saito 2008 paper was not identified by  
4 defendants for use today with Dr. Fisher.

5 Of course, in addition, there's no discussion of  
6 the interaction P values even in this discussion of the Saito  
7 paper. It's -- this discussion that they're pointing to isn't  
8 even about the reference that they're having the witness  
9 discuss. This is completely outside his expert report.

10 MS. HUTTNER: Your Honor, I'm not sure I  
11 understand the comment.

12 In paragraph 126 -- I'm sorry, paragraph 125,  
13 Dr. Fisher is discussing the Yokoyama studies responding to  
14 Dr. Ismail's discussion about Yokoyama in his report which I  
15 showed you a moment ago, and he is commenting on the  
16 statistical significance of the reduction in diabetic  
17 patients, and he specifically refers to Yokoyama.

18 The Saito article which is referenced in  
19 paragraph 126 also pertains to the JELIS study and to the same  
20 patient population that's discussed in Yokoyama.

21 So I'm not really sure what the issue is here or  
22 why there is any surprise here.

23 MR. SIPES: Your Honor, first of all, there is  
24 no disclosure of any testimony by Dr. Fisher about the  
25 interaction P values an the Yokoyama 2007 paper.

10:06:55 1 Even this discussion of Saito which is about a  
10:06:59 2 completely different analysis in a different paper doesn't  
10:07:02 3 talk about interaction P values. None of this disclosure has  
10:07:07 4 anything do with the testimony they're now putting up about  
10:07:10 5 interaction P values in Yokoyama 2007.

10:07:14 6 MS. HUTTNER: Your Honor, I just would note --

10:07:16 7 THE COURT: Ms. Huttner, point out the portion  
10:07:18 8 in the report that discusses interaction of the P values that  
10:07:22 9 Dr. Fisher has testified to.

10:07:24 10 MS. HUTTNER: There is no specific discussion of  
10:07:27 11 interaction P value. What there is is a statement that he  
10:07:31 12 disagrees with Dr. Ismail's statement that the Yokoyama  
10:07:37 13 results, the JELIS study results as to diabetics are  
10:07:41 14 essentially of no value.

10:07:43 15 THE COURT: But, in explaining -- let me try to  
10:07:46 16 understand because this is complex and I don't want to miss  
10:07:49 17 something here.

10:07:49 18 So in explaining why he disagrees -- so I'm  
10:07:52 19 looking paragraph 125. In explaining why Dr. Fisher disagrees  
10:07:56 20 with Dr. Ismail's statement about -- that JELIS did not find a  
10:08:02 21 statistically significant reduction in CV events in diabetes  
10:08:10 22 patients is incorrect, he criticized that statement by  
10:08:14 23 Dr. Ismail and said that the Yokoyama paper cite doesn't  
10:08:22 24 support that proposition.

10:08:23 25 And then he went on to say -- to identify that

1 one of the authors of Yokoyama, Saito, the author, performed  
2 another subanalysis, and they he explained what the  
3 subanalysis is.

4 So, in a way, Dr. Fisher's report explained why  
5 he disagrees with Dr. Ismail's reliance on the Yokoyama paper.  
6 So I agree with that. At least he referenced that and  
7 explained why he disagreed, but in explaining why he  
8 disagrees, he doesn't reference the P value.

9 MS. HUTTNER: Right. So Dr. Ishmail referred --  
10 I think I showed the paragraph where he refers to this hazard  
11 ratio which comes from this table that we're looking at in the  
12 exhibit, and same table contains the interaction P value which  
13 pertains to the same portion of Yokoyama that Dr. Ismail was  
14 discussing in his report.

15 THE COURT: So this is part of the problem  
16 because I haven't heard Dr. Ismail's testimony.

17 MS. HUTTNER: It makes it a little bit  
18 difficult, Your Honor, as you can imagine.

19 But I think I showed you -- and it's in  
20 paragraph -- I'm sorry, if we can put up DDX 9.115.

21 So if you look -- this is from Dr. Ismail's  
22 report. He references that hazard ration and the confidence  
23 interval, that comes from the table that was presented in  
24 DDX 9.116 which also contains the interaction P value.

25 So all of these values are to be looked at

10:09:56 1 together.

10:09:56 2 He was deposed I would note, Dr. Fisher, on this  
10:09:59 3 very point, and Mr. Sipes had every opportunity to ask for  
10:10:03 4 further explanation or what else it was in this article that  
10:10:08 5 Dr. Fisher was relying on the so I don't think there's any  
10:10:11 6 surprise here.

10:10:12 7 THE COURT: Hang on. Did Dr. Fisher testify to  
10:10:14 8 this issue in his deposition regardless of what's in his  
10:10:19 9 report? You said he was deposed on this issue.

10:10:21 10 MS. HUTTNER: He was asked about the confidence  
10:10:24 11 interval that Dr. Ismail cited in his report, and he was not  
10:10:28 12 asked any questions specifically about the interaction P  
10:10:31 13 value.

10:10:31 14 THE COURT: And that's the objection here is  
10:10:33 15 that the report does not disclose interactions between P  
10:10:36 16 values, and apparently he was not asked about that in his  
10:10:39 17 deposition, and now he's testifying to this issue for the  
10:10:42 18 first time.

10:10:43 19 MS. HUTTNER: Well, I think the point is that  
10:10:44 20 you can only discuss the significance of the confidence  
10:10:50 21 interval by taking into account all of the information that's  
10:10:53 22 presented in the same table which includes the interaction P  
10:10:56 23 value.

10:10:56 24 And, as I said, this is the table that  
10:11:01 25 Dr. Ismail was discussing in his report. And so all that

1 Dr. Fisher is going to explain is that you have to look at the  
2 data as a whole.

3 MR. SIPES: Your Honor, as the one who deposed  
4 Dr. Fisher, the point here that's come out of this it's very  
5 clear is that Dr. Ismail clearly disclosed his opinions in his  
6 report, and Dr. Fisher responded in his report.

7 In responding, he did not respond in any way by  
8 identifying the interaction P values. Instead he responded by  
9 pointing to yet a different article, an article that is not  
10 being discussed today that does not discuss interaction P  
11 values.

12 I had no opportunity to depose Dr. Fisher about  
13 interaction P values at all because it was not identified --  
14 you cannot find in his report the term interaction P values at  
15 all. I had no opportunity to go into this. This is a  
16 completely new blindsiding testimony about interaction P  
17 values.

18 MS. HUTTNER: I just -- I don't see how that  
19 could be true, Your Honor, because --

20 THE COURT: Well, can you point to anywhere in  
21 his report or his deposition testimony where he testified to  
22 the interactions between the P values?

23 MS. HUTTNER: No, Your Honor, that did not come  
24 up.

25 THE COURT: All right. Then I sustain the

objection.

I agree that Dr. Ismail in his report at paragraph 125 and 126 did discuss the Yokoyama paper and point out why he disagrees with Dr. Ismail's reliance on that paper in referring to the Saito paper.

But given the acknowledgement that he did not testify to the interactions between P values, and no where in his report does he specifically address this issue, I agree that the testimony exceeds the scope of the disclosure in his report, therefore this objection is sustained.

MR. SIPES: Thank you, Your Honor.

BY MS. HUTTNER:

Q Dr. Fisher, was there a subsequent analysis -- after the publication of Yokoyama, was -- was there a subsequent paper that looked at the -- the situation in Yokoyama with respect to -- in the JELIS study, rather, with respect to diabetic patients?

A Yes, there was.

Q And that paper was the Saito paper?

A Yes.

Q When was that published?

A In 2008.

Q And did you rely on the Saito paper in your report in relation to the meaning of the JELIS study as far as it pertained to diabetic patients?

10:13:18 1 A I did.

10:13:18 2 Q And what is it -- can you describe what's discussed in  
10:13:21 3 Saito.

10:13:22 4 A Well, Saito did subgroup analyses using the data from the  
10:13:28 5 original population in JELIS which was in total about 18,000  
10:13:37 6 subjects.

10:13:37 7 And by creating subgroups which included patients  
10:13:41 8 with diabetes, patients with different lipid profiles,  
10:13:46 9 patients who were obese, he separately evaluated the  
10:13:51 10 effectiveness of EPA to reduce the cardiovascular events as  
10:13:57 11 related to those -- to those factors.

10:14:00 12 Q And what did he conclude in that regard, Dr. Saito?

10:14:05 13 A He concluded that the group that had mixed dyslipidemia,  
10:14:12 14 which was defined as elevated triglycerides and low HDL, was  
10:14:18 15 particularly enriched in patients with diabetes, and that  
10:14:24 16 group, subgroup, had a risk reduction that was 53 percent and  
10:14:30 17 was statistically very significant.

10:14:34 18 Q Now, in Dr. Ismail's report, he also criticizes the  
10:14:40 19 design of the JELIS study, correct?

10:14:42 20 A Yes.

10:14:43 21 Q And I believe that's in paragraph 40 of his opening  
10:14:46 22 report?

10:14:46 23 A Yes.

10:14:47 24 MS. HUTTNER: Can we see DDX 9.18, please.

10:14:47 25

10:14:47 1 BY MS. HUTTNER:

10:14:53 2 Q Did you prepare a slide that summarizes your  
10:14:56 3 understanding of Dr. Ismail's issues with the JELIS study?

10:15:00 4 A Yes, this is the slide.

10:15:01 5 Q Briefly, if you could just explain what Dr. Ismail's --  
10:15:05 6 or your understanding of Dr. Ismail's opinions or criticisms  
10:15:09 7 of the JELIS study design.

10:15:10 8 A Yes, he points out these factors as undercutting the  
10:15:15 9 significance of the study, the validity of the study.

10:15:19 10 One, the fact that it was not placebo-controlled  
10:15:24 11 was -- was mentioned by him.

10:15:26 12 The other, the Japanese population consumes a higher  
10:15:31 13 amount of fish.

10:15:32 14 The third, the Japanese population uses lower doses  
10:15:36 15 of statins.

10:15:37 16 And the last one is that JELIS used a lower dose of  
10:15:41 17 purified EPA, 1.8 grams per day, than the indication of  
10:15:47 18 Vascepa or Lovaza which is 4 grams a day.

10:15:49 19 Q And did Dr. Mason -- I'm not going to go through the  
10:15:53 20 specifics, but did Dr. Mason also express criticism of the  
10:15:58 21 JELIS study in his report?

10:16:00 22 A He did.

10:16:00 23 Q And were his criticisms substantially along the lines set  
10:16:03 24 forth in Dr. Ismail's report?

10:16:05 25 A Yes, they were.

10:16:05 1 Q Do you agree with Dr. Ismail's and Dr. Mason's criticisms  
10:16:11 2 of the JELIS study design?

10:16:13 3 A That these are factors that invalidate JELIS, I do not  
10:16:17 4 agree.

10:16:17 5 Q Are these statements correct that the JELIS was not  
10:16:21 6 placebo-controlled, Japanese consumed more fish, and used  
10:16:25 7 lower doses of statin, and that the dose was lower in JELIS,  
10:16:32 8 those are all true, right?

10:16:33 9 A Those are all true.

10:16:34 10 Q Do you regard those as flaws in the design of JELIS?

10:16:37 11 A No.

10:16:38 12 Q And do you regard these factors as having any negative  
10:16:40 13 impact on the finding in JELIS that EPA resulted in a  
10:16:45 14 19 percent risk reduction in patients on stable statin  
10:16:49 15 therapy?

10:16:49 16 A No.

10:16:50 17 Q And, to your understanding, is there any difference  
10:16:53 18 between EPA and Vascepa from a chemical point of view?

10:16:57 19 A No, they're both highly-purified forms.

10:17:01 20 Q Now, did you -- as part of your work on this case, did  
10:17:03 21 you review certain materials that Amarin submitted to FDA in  
10:17:08 22 connection with what's been referred to in these proceedings  
10:17:12 23 as a special protocol assessment agreement with FDA?

10:17:16 24 A I did.

10:17:16 25 Q And did you also review certain materials that Amarin

10:17:19 1 submitted to FDA in connection with the FDA's evaluation of  
10:17:25 2 whether or not to continue that special protocol assessment  
10:17:29 3 agreement?

10:17:29 4 A I reviewed that.

10:17:30 5 Q And in connection with Amarin's appeal from their  
10:17:33 6 decision to terminate that agreement?

10:17:35 7 A That as well.

10:17:37 8 Q And, in your opinion, were the statements that Amarin --  
10:17:42 9 let me just ask you the foundation question. Did those  
10:17:45 10 materials discuss the JELIS study?

10:17:47 11 A They did.

10:17:47 12 Q And were Amarin's statements to FDA about JELIS in those  
10:17:52 13 materials that you reviewed consistent with Dr. Ismail's  
10:17:56 14 criticisms of JELIS as set forth in DDX 9.18?

10:18:00 15 A They were not consistent with his criticisms.

10:18:04 16 MS. HUTTNER: Can we go to DX 2106, please.

10:18:09 17 Actually, let's go to DDX 9.19.

10:18:09 18 BY MS. HUTTNER:

10:18:15 19 Q Okay. This slide is taken -- the snapshot is taken from  
10:18:22 20 DX 2106, which is the transcript from October 16th, 2013  
10:18:29 21 meeting of the FDA Advisory Committee that was convened in  
10:18:34 22 connection with Amarin's special protocol assessment  
10:18:37 23 agreement. Is this one of the documents you read, sir?

10:18:39 24 A Yes.

10:18:40 25 Q And do you rely on it in your report in this case?

10:18:43 1 A I do.

10:18:44 2 MS. HUTTNER: Your Honor, we would move DX 2106  
10:18:47 3 into evidence.

10:18:48 4 MR. SIPES: No objection, Your Honor.

10:18:48 5 THE COURT: 2106 is admitted.

10:18:48 6 (Defendant's Exhibit 2106 received in  
10:18:48 evidence.)

10:18:48 7 BY MS. HUTTNER:

10:18:52 8 Q Okay. So in the snapshot on the right, you have pulled  
10:18:56 9 out some testimony that appears on pages 217 to 219 of DX  
10:19:03 10 2106, and let me ask you, who is speaking in this transcript?

10:19:09 11 A Dr. Eliot Brinton.

10:19:11 12 Q Who is Dr. Eliot Brinton?

10:19:14 13 A He's a well-known lipidologist. I think he's based in  
10:19:18 14 Utah.

10:19:18 15 Q It says -- in the first paragraph he says, "I'm on the  
10:19:23 16 REDUCE-IT steering committee and am receiving travel  
10:19:30 17 reimbursement from Amarin."

10:19:32 18 Is it your understanding that Dr. Brinton was one of  
10:19:35 19 the people in charge of the REDUCE-IT study?

10:19:38 20 A Well, the steering committee does oversee the overall  
10:19:42 21 study so, yes.

10:19:43 22 Q And did -- is Dr. Brinton also one of the co-authors of  
10:19:50 23 the article that we've seen a few times in this case that  
10:19:55 24 Dr. Bhatt published, Dr. Bhatt is the lead author, that was  
10:19:58 25 published in the *New England Journal of Medicine* concerning

1 the REDUCE-IT study?

2 A Yes, he is a co-author.

3 Q Okay. In this transcript he's testifying why he thinks  
4 that -- that the FDA should continue the special protocol  
5 agreement, correct?

6 A Yes.

7 Q And the first thing he says is, "I think we need to  
8 consider more of the data on JELIS."

9 And in the highlighted paragraphs he goes on to say,  
10 "My rationale for approving the expanded  
11 indication for Vascepa is basically the clinical  
12 trial evidence for JELIS, which is a pure EPA study,  
13 therefore very similar to and I think relevant to  
14 Vascepa."

15 And then he goes on, "Does Vascepa actually  
16 equal Epadel? They're both greater than 98 percent  
17 pure EPA ethyl ester. There's no known chemical  
18 difference between the two. So I think that JELIS is  
19 very relevant to the question today."

20 In the last paragraph he says, "Therefore,  
21 in my opinion, even though PROBE design open label is  
22 potentially problematic, I think that it is much less  
23 problematic than it would have been if that had not  
24 been the case. So I think it's important to realize  
25 that hard MACE was definitely reduced in this study."

10:21:10 1 Is it your understanding -- what is your  
10:21:12 2 understanding of what Dr. Brinton is saying here regarding the  
10:21:16 3 relationship between JELIS and Vascepa?

10:21:18 4 A Well, he is saying that the results that were obtained in  
10:21:23 5 JELIS should be obtained in the REDUCE-IT study because it's  
10:21:29 6 essentially the same compound that's being tested.

10:21:32 7 Q Did Dr. Brinton in his remarks to the advisory committee  
10:21:38 8 discuss -- or did he indicate that he felt that the JELIS  
10:21:42 9 study was flawed?

10:21:43 10 A No. He's speaking about it in a very positive way, and  
10:21:49 11 particularly on the point -- Dr. Ismail's first point about  
10:21:52 12 the placebo control.

10:21:54 13 He brings up the -- this issue, although it may not  
10:21:58 14 be immediately obvious, particularly to the nonspecialist,  
10:22:01 15 when he discusses the PROBE design.

10:22:04 16 So the PROBE design is an established clinical  
10:22:09 17 research method which stands for Prospective Randomized Open  
10:22:19 18 Labeled Blinded Endpoint design, and what that means is that  
10:22:24 19 it simulates actually what happens in his doctor's office.

10:22:28 20 And some people believe actually these are much more  
10:22:32 21 relevant to the ultimate application of the findings because  
10:22:36 22 patients will be getting the drug in the context of the  
10:22:38 23 doctor's office and they clearly know who's getting the drug  
10:22:41 24 and who isn't.

10:22:43 25 So the fact that it was open label, which means that

1 both the treatment group and the nontreatment group knew they  
2 were on or off the EPA was not a concern to him because what's  
3 most important is the determination of the end points.

4 So the P -- the BE, blinded endpoint, means that the  
5 cardiovascular events were what's called adjudicated by  
6 experts, they weren't just patient reports, and the experts  
7 didn't know whether the event occurred in one group or the  
8 other, and so there's no bias in determining what the endpoint  
9 is, which is why he uses the word hard MACE, hard major  
10 adverse cardiovascular events, because these essentially were  
11 certified by experts.

12 So he takes the evidence in JELIS to indicate that  
13 by his criteria that these hard end points were definitely  
14 reduced in this study which used the same agent as what's  
15 being used in REDUCE-IT.

16 Q Do you agree with just Dr. Brinton's statements about  
17 JELIS in his testimony to the FDA?

18 A Yes.

19 Q And, by the way, do you know whether Dr. Brinton was  
20 under oath?

21 A Yes, he was.

22 Q In your opinion, is Dr. Brinton's testimony to FDA about  
23 JELIS consistent with Dr. Ismail's opinions in this case?

24 A Not at all.

25 Q Let's go to page 47 of this same transcript, DX 2106, and

10:24:32 1 we're looking DDX 9.20. Is this another excerpt from the  
10:24:37 2 transcript of the advisory committee hearing?

10:24:39 3 A It is.

10:24:40 4 Q And who is speaks in this portion of the transcript?

10:24:41 5 A Dr. Michael Miller.

10:24:42 6 Q I think, as we've heard, Dr. Miller was a claim  
10:24:45 7 construction for Amarin in this case, correct?

10:24:48 8 A Yes.

10:24:45 9 Q Claim construction expert for Amarin in this case.

10:24:45 10 A Yes.

10:24:49 11 Q Is that your understanding as well?

10:24:50 12 A Yes.

10:24:51 13 Q Do you know Dr. Miller?

10:24:52 14 A I know him through the field. He's a well-known  
10:24:57 15 lipidologist based in Maryland.

10:24:59 16 Q And what did Dr. Miller tell the FDA Advisory Committee  
10:25:04 17 about the design of the JELIS study and results of the JELIS  
10:25:07 18 study as they relate to Vascepa?

10:25:10 19 A Well, if we look in the top left, he's clearly advocating  
10:25:16 20 that more attention is paid to the JELIS study in order to  
10:25:21 21 support the application that Amarin has made.

10:25:26 22 Q Are you referring to Dr. Miller's statement that,

10:25:30 23 "I would like to discuss the JELIS study in  
10:25:33 24 some more detail since this is the study that has  
10:25:37 25 demonstrated additional cardiovascular benefit of a

10:25:40 1 therapy added to a statin. And this study used EPA,  
10:25:44 2 the active ingredient used in the ANCHOR study"?

10:25:48 3 A Yes, and, as we know, the same active ingredient is used  
10:25:52 4 in the REDUCE-IT study as well.

10:25:54 5 Q Just so we have a context here, do you have an  
10:25:57 6 understanding what Dr. Miller was referring to here when he  
10:26:01 7 used the term ANCHOR study?

10:26:03 8 A This was a study, not an endpoint study, but this was a  
10:26:08 9 lipid efficacy study that was done in patients with -- that  
10:26:14 10 were in the high triglyceride groups that had -- were treated  
10:26:19 11 with a statin.

10:26:20 12 So this was looking at the combination of a statin  
10:26:24 13 and highly-purified EPA on the lipid profile in those  
10:26:30 14 patients.

10:26:30 15 Q The highly-purified EPA that was examined in the ANCHOR  
10:26:36 16 study was Vascepa, correct?

10:26:37 17 A Yes.

10:26:39 18 Q And the ANCHOR study was an Amarin study?

10:26:41 19 A Yes, it is, was.

10:26:42 20 Q And do you have an understanding as to whether there's  
10:26:45 21 any connection between the ANCHOR study and REDUCE-IT?

10:26:48 22 A Yes. The same type of patients were then studied in  
10:26:52 23 REDUCE-IT but now from the perspective of cardiovascular risk  
10:26:55 24 reduction.

10:26:56 25 Q And Dr. Miller also said in this excerpt from the

1 transcript that,

2 "While looking at patients with elevated  
3 baseline triglyceride levels similar to those seen in  
4 ANCHOR, we see an even more pronounced effect."

5 And he goes on to state, "Dr. Saito found  
6 that mixed dyslipidemia patients with triglycerides  
7 greater than 150 milligrams per deciliter gained an  
8 even greater clinical benefit from the addition of  
9 EPA therapy."

10 Is it your understanding that Dr. Miller is  
11 referring in this portion of the transcript to the same Saito  
12 article that you discussed in your testimony?

13 A Yes, it's the same article.

14 Q And what is he saying about what -- the findings in Saito  
15 here?

16 A Well, that they are very relevant to ANCHOR and then, by  
17 extension, to REDUCE-IT because in the patient population of  
18 similar characteristics there was a very significant reduction  
19 in cardiovascular events.

20 And as we reviewed a few minutes ago, this was a  
21 53 percent reduction in that particular group in the JELIS  
22 study.

23 Q And then in the last paragraph, if we can go back to DDX  
24 9.20, in the last paragraph that you've excerpted --

25 MS. HUTTNER: The whole paragraph, please,

1 Steven.

2 BY MS. HUTTNER:

3 Q In the last paragraph of his remarks that you've  
4 excerpted in DDX 9.20, Dr. Miller goes on to discuss the Saito  
5 study in some more detail, correct?

6 A Yes.

7 Q And he says,

8 "Over 950 dyslipidemic patients who had  
9 baseline triglycerides similar to ANCHOR demonstrated  
10 a 53 percent reduction in major coronary events over  
11 statin therapy alone. These results suggest that  
12 long-term treatment with EPA has a morbidity benefit  
13 for patients with elevated triglycerides when  
14 combined with statin and diet therapy."

15 And do you understand him to talking there -- to  
16 be suggesting there that the combination of the JELIS and  
17 Saito to him means that -- suggests to him that EPA would have  
18 a potential benefit in all patients with elevated -- severely  
19 elevated triglycerides?

20 A Yes, he says --

21 Q I'm sorry, elevated triglycerides.

22 A With elevated -- yeah, with elevated triglycerides when  
23 combined with statin and diet therapy, because refers to EPA,  
24 and it's the same EPA in the JELIS as it is in ANCHOR as it is  
25 in REDUCE-IT. So he just attributes this effect to EPA.

10:29:36 1 Q Do you agree, by the way, with what Dr. Miller said to  
10:29:39 2 FDA about JELIS --

10:29:39 3 A I do.

10:29:40 4 Q -- as it relates to Vascepa?

10:29:42 5 A I do.

10:29:43 6 Q In your opinion, are Dr. Ismail's opinions about JELIS  
10:29:46 7 consistent with Dr. Miller's testimony about JELIS to FDA?

10:29:49 8 A No.

10:29:52 9 MS. HUTTNER: Your Honor, I'm about to move on.  
10:29:54 10 I don't know if you want to take the mid morning break now or  
10:29:57 11 you want me to continue.

10:29:58 12 THE COURT: I think you read my mind. Let's  
10:29:59 13 take our morning break at this time. Thank you.

10:47:51 14 (A recess was taken.)

10:47:51 15 THE COURT: Please be seated.

10:47:54 16 MS. HUTTNER: May I resume, Your Honor?

10:47:56 17 THE COURT: Yes.

10:47:58 18 MS. HUTTNER: May I have DDX 9.21, please.

10:47:58 19 BY MS. HUTTNER:

10:48:08 20 Q Dr. Fisher, DDX 9.21 is an excerpt from DX 1836, which is  
10:48:16 21 in evidence, and this particular excerpt is from page 81 of DX  
10:48:23 22 1836, correct?

10:48:24 23 A Yes.

10:48:24 24 Q And this is a part of Amarin's February 2014 dispute  
10:48:32 25 resolution request in connection with the -- I'm sorry,

10:48:40 1 special protocol assessment agreement that Amarin had with  
10:48:45 2 FDA?

10:48:45 3 A Yes.

10:48:46 4 Q And in this excerpt that you've pulled out, Amarin says,  
10:48:51 5 "Plasma EPA levels that resulted in JELIS  
10:48:55 6 from EPA 1.8 grams per day in a Japanese population  
10:49:00 7 are approximately equal to the plasma EPA levels  
10:49:04 8 observed in the ANCHOR study with 4 grams per day  
10:49:07 9 Vascepa in United States-based population."

10:49:12 10 Does that understanding, to your understanding,  
10:49:12 11 pertain to one of the aspects of the JELIS study that  
10:49:18 12 Dr. Ismail criticized in his report?

10:49:18 13 A Yes, it does.

10:49:19 14 Q Which one does it pertain to, which criticism?

10:49:21 15 A That the dose was 1.8 grams per day, which is lower than  
10:49:27 16 the 4 grams per day of Vascepa in the ANCHOR study.

10:49:32 17 Q And am I correct in understanding that Dr. Ismail felt  
10:49:35 18 that the dose was too low to make the JELIS comparable or  
10:49:39 19 predictive of the outcomes of the REDUCE-IT study?

10:49:42 20 A Yes.

10:49:42 21 Q And in this statement Amarin goes on to say,  
10:49:48 22 "Furthermore, there is a precedent set by the  
10:49:52 23 ACC/AHA for applying results from an exclusively  
10:49:55 24 Japanese population to a United States-based  
10:49:57 25 population," and goes on to conclude, "These points

10:50:01 1 strongly support the consideration of JELIS study  
10:50:05 2 results in evaluating the potential CV benefits of  
10:50:10 3 Vascepa therapy."

10:50:11 4 The second sentence there that talks about the  
10:50:14 5 precedent set by the ACC and AHA for applying the results of a  
10:50:17 6 study exclusively conducted in Japanese patients, does that  
10:50:21 7 relate to another of Dr. Ismail's criticisms of JELIS?

10:50:27 8 A Yes, it does.

10:50:28 9 Q And that criticisms was that you can't extrapolate from  
10:50:32 10 the results of -- in a 100 percent Japanese population to what  
10:50:33 11 results you'd get in a western population?

10:50:34 12 A Right, that was his implication.

10:50:36 13 Q And is Amarin -- in this statement to FDA is Amarin  
10:50:39 14 agreeing with Dr. Ismail's opinion?

10:50:42 15 A They are not.

10:50:43 16 Q Can you explain why you say that.

10:50:45 17 A Well, for the first criticism about the dose, what they  
10:50:51 18 point out is that the achieved levels in the plasma or the  
10:50:56 19 blood are actually the same in the JELIS study and the ANCHOR  
10:50:59 20 study, and that, of course, is the effective concentration of  
10:51:05 21 the compound that the cells in the body will see.

10:51:07 22 So on the basis of what the exposure of the cells is  
10:51:12 23 in either study to highly-purified EPA, they are nearly the  
10:51:19 24 same.

10:51:20 25 The second point, I think we'll talk about that

1 study soon, so-called MEGA study, this was a study that was  
2 looking at a primary prevention strategy in the Japanese  
3 population that turned out to be one of only three studies  
4 that were used by the ACC and AHA, and that stands for the  
5 American College of Cardiology and American Heart Association,  
6 two extremely influential organizations.

7 So that was taken as evidence for their  
8 recommendations in the U.S. population. So, in other words,  
9 the results in that study done in Japan were judged by the ACC  
10 and AHA to be relevant to the United States population.

11 Q And do you agree with Amarin's statements in -- that are  
12 called out in DDX 9.21, do you agree with what Amarin was  
13 telling FDA about the JELIS study?

14 A Yes, these are statements of fact.

15 Q All right. Let me direct your attention to page 73 of  
16 the same document, and that is DDX 9.23.

17 A Yes.

18 Q We need to put it up on the screen first.

19 Okay. This is the excerpt from page 73 of DX 1836?

20 A Yes.

21 Q And in this same document, what is Amarin discussing with  
22 FDA in this snapshot?

23 A This is on the point of the dose of the statin that was  
24 used in JELIS, that it was relevant to an appropriate --  
25 relevant to the, again, studies in the U.S. and was

10:53:35 1 appropriate.

10:53:38 2 Q Do these comments relate to Dr. Ismail's criticism that  
10:53:42 3 the statin dose used in JELIS was too low?

10:53:45 4 A Yes.

10:53:46 5 Q And can you explain, I see the -- in the second paragraph  
10:53:49 6 it says -- it refers to the MEGA trial; is that right?

10:53:53 7 A Yes.

10:53:54 8 Q That's the same study you discussed a moment ago?

10:53:57 9 A Yes.

10:53:57 10 Q Amarin concludes in this statement,

10:53:59 11 "Taken together, these points demonstrate  
10:54:02 12 that the JELIS patients were on a dose of pravastatin  
10:54:05 13 that is recognized as adequate to treat LDL-C  
10:54:08 14 according to contemporary Japanese- and United  
10:54:11 15 States-based guidelines."

10:54:12 16 Is that statement accurate?

10:54:18 17 A Yes, it is.

10:54:18 18 Q Do Amarin's comments to FDA in this document about the  
10:54:22 19 adequacy of the statin dose in the JELIS trial, are they  
10:54:26 20 consistent with Dr. Ismail's opinions in this case?

10:54:29 21 A They are not.

10:54:30 22 Q And can you explain Amarin's reference to the Japanese-  
10:54:37 23 and United States-based guidelines, do you have an  
10:54:40 24 understanding what they're referring to there?

10:54:44 25 A Yes. The first part is essentially acknowledging that

10:54:49 1 JELIS followed the guidelines that were in place by the  
10:54:55 2 authoritative organization, the Japanese Atherosclerosis  
10:54:59 3 Society.

10:55:00 4 And the second part is that the guidelines that were  
10:55:07 5 in effect in Japan that influenced the design of the MEGA  
10:55:13 6 trial, were found -- the results of that trial were found  
10:55:19 7 relevant to primary prevention guidelines that the ACC and AHA  
10:55:28 8 formulated.

10:55:29 9 So that's why it's taken together, that the  
10:55:32 10 guidelines that were followed in Japan were adjudged to be  
10:55:38 11 relevant to not only the U.S. population, but formed the basis  
10:55:43 12 for guidelines in the U.S., which meant that the dose of the  
10:55:50 13 pravastatin was recognized as adequate or appropriate to treat  
10:55:54 14 LDL cholesterol according to contemporary Japanese- and  
10:55:59 15 U.S.-based guidelines.

10:55:59 16 Q And, in your opinion, were the patients enrolled in the  
10:56:02 17 JELIS study on stable statin therapy?

10:56:05 18 A Yes, they were.

10:56:06 19 Q Now, FDA -- or do you understand that FDA eventually  
10:56:10 20 rejected -- that rescinded the special protocol assessment  
10:56:14 21 agreement, and there was an appeal by Amarin which was  
10:56:17 22 ultimately lost?

10:56:18 23 A Yes, I understand that.

10:56:19 24 Q And that happened in about 2013; is that correct?

10:56:23 25 A Yes.

10:56:23 1 Q In that time frame?

10:56:24 2 Have you seen any statements by any of Amarin's  
10:56:27 3 experts in this case about JELIS since Amarin lost their  
10:56:31 4 appeal of the FDA's -- of the special protocol assessment  
10:56:35 5 agreement?

10:56:35 6 A I have seen it.

10:56:38 7 MS. HUTTNER: Can I have DDX -- I'm sorry, DDX  
10:56:38 8 9.25.

10:56:38 9 BY MS. HUTTNER:

10:56:45 10 Q DDX 9.25 is an excerpt from DX 12 -- I'm sorry, DX 2139,  
10:56:57 11 and I want to identify DX 2139. What is DX 2139?

10:57:04 12 A This is a transcript of a meeting that was organized by a  
10:57:12 13 company called Slingshot in which they invite experts, opinion  
10:57:20 14 leaders in different areas, to interact with investors.

10:57:22 15 Q And is this one of the documents -- DX 2139, is this one  
10:57:27 16 the documents that you relied on in your expert report?

10:57:30 17 A It is.

10:57:31 18 Q And you've reviewed this document?

10:57:32 19 A I have.

10:57:34 20 MS. HUTTNER: Your Honor, we would move DX 2139  
10:57:36 21 into evidence.

10:57:37 22 MR. SIPES: No objection, Your Honor.

10:57:39 23 THE COURT: DX 2139 is admitted.

10:57:39 24 (Defendant's Exhibit 2139 received in  
10:57:39 evidence.)  
10:57:39 25

10:57:39 1 BY MS. HUTTNER:

10:57:44 2 Q Now, in this particular interview, the interviewee was  
10:57:48 3 Dr. Matthew Budoff, correct?

10:57:48 4 A Yes, it is.

10:57:49 5 Q And that's the same Dr. Budoff has testified earlier  
10:57:52 6 these proceedings?

10:57:52 7 A Yes.

10:57:53 8 Q And the call leader asks Dr. Budoff, he says,

10:57:57 9 "I think you had mentioned early in the call  
10:58:00 10 a Japanese outcome study. I can read a little bit  
10:58:04 11 about it. Let's see, it was a low-density  
10:58:06 12 prescription pure EPA added to statin therapies has  
10:58:11 13 been shown to produce cardiovascular event reduction  
10:58:14 14 with moderately elevated triglycerides by 19 percent  
10:58:18 15 in the overall population and 53 percent in the  
10:58:21 16 subgroup in patients similar to the population of  
10:58:25 17 REDUCE-IT. So I was just wondering, is that  
10:58:27 18 something that influences your thinking on  
10:58:28 19 REDUCE-IT?"

10:58:29 20 And just -- then he goes on to say, "I was  
10:58:33 21 just wondering on if you had any view on what the  
10:58:37 22 Japanese study means."

10:58:39 23 Do you recall the call leader there to be  
10:58:44 24 referring to the JELIS study?

10:58:44 25 A Yes, he is.

Q And Dr. Budoff in response to the question asking for his views on how the JELIS study relates to REDUCE-IT says,

"Yeah, absolutely. No, I'm not expecting 53 percent. But I do think that there's likelihood of the trial being more positive somewhat on that analysis."

What -- what is your -- based on your review of this article, is it your impression that Dr. Budoff believed in 2017 -- by the way, 2017 -- this interview took place before the results of REDUCE-IT were announced, correct?

A Yeah, two years before.

Q Okay. And what is your understanding of what Dr. Budoff was saying here insofar as what emphasis he felt should be placed on the JELIS study in relation to the expected outcome of REDUCE-IT?

A He felt that the results were quite positive, and he would expect a positive result in REDUCE-IT.

But, of course, until he had the actual numbers, he couldn't predict whether it was going to be 53 percent or some other number, but it would be a positive study based on the success of the -- in the patient subgroup that most resembled the REDUCE-IT population.

Q And Dr. Budoff was not only an expert witness here, but he was actually involved in the REDUCE-IT trial, was he not?

A Yes.

11:00:06 1 Q Now, Dr. Budoff gave a second interview to Slingshot  
11:00:14 2 Insights in 2018, correct?

11:00:16 3 A Yes.

11:00:16 4 Q And that interview took place on July 17th, 2018?

11:00:21 5 A Uh --

11:00:23 6 Q We can look.

11:00:24 7 A Yeah, I have to look at the date of the transcript.

11:00:28 8 MS. HUTTNER: Okay. Could we have DDX 9.37,  
11:00:32 9 please.

11:00:32 10 BY MS. HUTTNER:

11:00:33 11 Q Okay, and, again, let's identify for the record, DX 2140  
11:00:38 12 is a copy of a second Slingshot interview from July 17th,  
11:00:46 13 2018, that you relied on in your expert report?

11:00:48 14 A Yes.

11:00:48 15 Q And you've reviewed that article?

11:00:50 16 A I have.

11:00:51 17 MS. HUTTNER: Your Honor, we would move DX 2140  
11:00:54 18 into evidence.

11:00:55 19 MR. SIPES: No objection, Your Honor.

11:00:56 20 THE COURT: 2140 is admitted.

11:00:56 21 (Defendant's Exhibit 2140 received in  
11:00:56 22 evidence.)

11:00:56 22 BY MS. HUTTNER:

11:01:00 23 Q Okay. Now, in this transcript which is -- it's about  
11:01:04 24 almost a year later after the first interview, right?

11:01:08 25 A Yes.

11:01:08 1 Q At this point in time, in July of 2018, we still had no  
11:01:11 2 results publically announced yet from REDUCE-IT yet, correct?

11:01:15 3 A It was still a year off, yes.

11:01:16 4 Q And it was a blinded study so Dr. Budoff wouldn't have  
11:01:19 5 access to the data from the REDUCE-IT study, correct?

11:01:23 6 A Correct.

11:01:23 7 Q So in this interview, in the snapshot, which is from  
11:01:29 8 page 15 of DX 2140, the call leader says,

11:01:34 9 "If you had to put odds on this coming out as  
11:01:36 10 a win for Vascepa and the REDUCE-IT study, a  
11:01:39 11 statistically significant, clinically meaningful risk  
11:01:43 12 reduction, zero to 100 percent, what sort of odds of  
11:01:47 13 success would you give this study?"

11:01:49 14 How did Dr. Budoff respond to that question?

11:01:52 15 A He said he'd give it about 85 percent.

11:01:55 16 Q And, in your experience, is that a robust prediction when  
11:01:59 17 you're talking about clinical trials?

11:02:00 18 A Well, we're in Reno, Nevada. If someone gave me an  
11:02:05 19 85 percent prediction, I would go across to the casino very  
11:02:08 20 quickly. So, yes, to be more formal, this is a very high  
11:02:12 21 degree of optimism.

11:02:15 22 MS. HUTTNER: If we can go now to PX 272, which  
11:02:22 23 is -- actually, let's go to DDX 9.24.

11:02:22 24 BY MS. HUTTNER:

11:02:28 25 Q Okay. Now, on the left in DDX 9.24 is a picture of the

11:02:33 1 front page from PX 272 which is in evidence. Do you recognize  
11:02:39 2 that as the Bhatt article this was published in 2019  
11:02:42 3 announcing the findings in the REDUCE-IT study?

11:02:46 4 A I do.

11:02:46 5 Q And you read that article?

11:02:48 6 A I did.

11:02:48 7 Q And in this excerpt that is in the snapshot, is Dr. Bhatt  
11:02:54 8 discussing the JELIS article?

11:02:55 9 A He is.

11:02:56 10 Q And Dr. Bhatt -- by the way, what was his role in  
11:03:00 11 relation so REDUCE-IT as far as you're aware?

11:03:02 12 A He was the study leader.

11:03:04 13 Q And what does -- what does Dr. Bhatt -- what does  
11:03:09 14 Dr. Bhatt say in this *New England Journal of Medicine* article  
11:03:15 15 about the JELIS study in relation to REDUCE-IT?

11:03:19 16 A Well, first, he emphasizes its, we'll say, credibility  
11:03:23 17 because he says,

11:03:24 18 "JELIS...showed that the risk of the ischemic  
11:03:28 19 events was significantly lower in the group that  
11:03:30 20 received the combination treatment than in the group  
11:03:34 21 that received statin therapy alone."

11:03:37 22 Then he goes on to compare JELIS to REDUCE-IT  
11:03:45 23 and basically implying that REDUCE-IT confirms the results in  
11:03:52 24 the previous study.

11:03:54 25 And one reason for this, as we discussed a few

1 minutes ago, is that the similarity in the blood levels of  
2 EPA, they were essentially the same in JELIS as they are in  
3 the ANCHOR study, as well as what was achieved in the  
4 REDUCE-IT study.

5 Q In your opinion, are Dr. Bhatt's statements about JELIS  
6 in PX 272 consistent with Dr. Ismail's criticism of JELIS in  
7 his report?

8 A No.

9 MS. HUTTNER: All right. Let's go back to  
10 DDX 9.116. We've seen this slide a couple times before.

11 BY MS. HUTTNER:

12 Q This is the summary of Dr. Ismail's opinions in this  
13 case. And I want to talk now about Dr. Ismail's opinion that  
14 the results in REDUCE-IT were unexpected because other  
15 clinical trials in diabetics involving triglyceride-lowering  
16 agents had failed to show a cardiac benefit.

17 First of all, do you agree with Dr. Ismail that the  
18 results of the REDUCE-IT study were unexpected?

19 A No, I do not agree.

20 Q I'm sorry. And -- would you agree with Dr. Ismail that  
21 the failure, as he calls it, of other cardiac outcome studies  
22 involving triglyceride-lowering agents was a basis upon which  
23 one would project that the REDUCE-IT study would fail?

24 A No, I don't agree with that either.

25 Q All right. Now, the studies -- what are the studies, the

11:05:38 1 prior studies, that Dr. Ismail characterizes as a failure?

11:05:42 2 A There were four. One is ACCORD, the other one is FIELD,  
11:05:48 3 there's ASCEND, and there's ORIGIN.

11:05:52 4 Q Okay. Now, let's talk first about the ACCORD trial.  
11:05:57 5 First of all, what was the ACCORD trial looking at?

11:06:00 6 A First -- all those trials I just mentioned were done in  
11:06:04 7 diabetics just so I don't keep repeating that.

11:06:07 8 The ACCORD trial was looking at the benefit of using  
11:06:12 9 a fenofibrate to reduce the risk of cardiovascular events in a  
11:06:20 10 diabetic population.

11:06:22 11 Q And was that in combination with a statin?

11:06:24 12 A Yes, there was statin use as well.

11:06:27 13 Q What was the dose used in the ACCORD study?

11:06:30 14 A The dose --

11:06:31 15 Q I'm sorry, you said it was fenofibrate study?

11:06:35 16 A Yes.

11:06:36 17 Q I'll withdraw the question.

11:06:37 18 Did Amarin discuss the ACCORD trial in any of its  
11:06:41 19 submissions to FDA relating to the special protocol assessment  
11:06:45 20 agreement?

11:06:46 21 A It did.

11:06:56 22 MS. HUTTNER: Can we go back to DX 1836, and can  
11:07:00 23 you pull up DDX 9.27, Mr. Gross.

11:07:00 24 BY MS. HUTTNER:

11:07:02 25 Q DX 1836 is in evidence, and this is from page 44 of that

11:07:06 1 exhibit, correct?

11:07:06 2 A Yes.

11:07:07 3 Q And the snapshot on the screen are Amarin's comments  
11:07:15 4 about the ACCORD study to FDA, correct?

11:07:19 5 A Yes.

11:07:19 6 Q What did Amarin tell FDA about the ACCORD study as far as  
11:07:24 7 whether it was relevant to their consideration of a cardiac  
11:07:29 8 indication for Vascepa?

11:07:30 9 A It's a little complicated, as we'll go through, but  
11:07:33 10 basically Amarin is telling the FDA that there are certain  
11:07:38 11 features of the ACCORD study that made it not very relevant to  
11:07:46 12 REDUCE-IT.

11:07:47 13 Q Okay. And in this snapshot, Amarin says,

11:07:53 14 "There are two unusual design components of  
11:07:56 15 the Accord lipid protocol that minimize the relevance  
11:07:58 16 of this study and are relevant to this discussion."

11:08:00 17 And it goes on in the next sentence to talk  
11:08:03 18 about the ACCORD study, right?

11:08:08 19 A Yes.

11:08:08 20 Q And it says there that the.

11:08:11 21 "...open-label simvastatin therapy was  
11:08:14 22 initiated at randomization (baseline) and 40 percent  
11:08:18 23 of patients were statin-naive at baseline."

11:08:23 24 In simple terms, what is Amarin saying there.

11:08:25 25 A Well, the difference between ACCORD and, say, ANCHOR or

1 REDUCE-IT, is that the patients before the study actually  
2 began with the EPA, there was a stabilized use of the statin.

3 Here, they point out that the simvastatin use was  
4 initiated at randomization, but that 40 percent of the  
5 patients were statin-naive at baseline, and then, as the study  
6 progressed, there were more people who became statin treated.  
7 So it was a bit of a moving target, so to speak.

8 So they -- they don't have comparable statin  
9 stabilized values at baseline in the ACCORD study.

10 THE COURT: Might I interject for moment?

11 Dr. Fisher, does statin-naive at baseline mean  
12 they were not on statin at baseline?

13 THE WITNESS: Yes, that's what that means.

14 BY MS. HUTTNER:

15 Q Amarin goes on in this same excerpt, and I'm focusing now  
16 on the next highlighted portion, to say,

17 "In fact, statin-treated (placebo)  
18 triglycerides levels at four months dropped to  
19 approximately 150 milligrams per deciliter and  
20 continued to drop" -- I'm sorry, "and continued to  
21 drop over the course of the study, meaning even fewer  
22 patients had triglycerides levels above normal and  
23 further minimizing the relevance of this study in  
24 establishing the CV benefit of TG-lowering in  
25 patients with persistent hypertriglyceridemia despite

11:09:59 1           statin therapy."

11:10:01 2                   And then in the last sentence Amarin says,  
11:10:03 3           "In light of there being no baseline  
11:10:05 4           statin-stabilized triglycerides levels for this  
11:10:08 5           study, it is difficult to understand how DMEP  
11:10:11 6           justifies using it to establish a lack of CV benefit  
11:10:14 7           to TG-lowering in statin-treated patients with  
11:10:17 8           persistent hypertriglyceridemia."

11:10:20 9                   In reference to that statement, what -- what  
11:10:24 10          is -- what is the gist of Amarin is saying here about  
11:10:28 11          triglyceride levels in the ACCORD study as compared to the  
11:10:33 12          REDUCE-IT study?

11:10:34 13          A     Right. Well, in the placebo or control group, there were  
11:10:39 14          fewer and fewer subjects who had hypertriglyceridemia, so you  
11:10:44 15          couldn't really compare the effects of the treatment with  
11:10:49 16          regard to the effects on triglyceride levels because, as he  
11:10:54 17          points out, that they were -- there was a continued drop over  
11:11:00 18          the course of the study in the triglyceride levels.

11:11:03 19          Q     So based on those triglyceride levels in the ACCORD  
11:11:07 20          study, would you be anticipating cardiac risk?

11:11:11 21          A     It would be hard to establish it. I agree with the --  
11:11:15 22          with the Amarin statement that given these considerations, it  
11:11:21 23          would be hard to establish a lack of CV benefit to TG-lowering  
11:11:27 24          in statin-treated patients.

11:11:29 25          Q     In the last sentence where Amarin says to FDA,

11:11:33 1 "It's difficult to understand how DMEP  
11:11:36 2 justifies using the ACCORD study to establish a lack  
11:11:39 3 of CV benefit to TG-lowering in statin-treated  
11:11:43 4 patients,"

11:11:44 5 the DMEP, do you know what that's referring to there?

11:11:47 6 A That's the division they were on, the advisory documents,  
11:11:50 7 committee documents, that's the Division of the FDA that  
11:11:54 8 oversees endocrinology metabolism agents.

11:12:01 9 MS. HUTTNER: Now, if we can go to DDX 9.28.

11:12:01 10 BY MS. HUTTNER:

11:12:07 11 Q This is an excerpt from the same exhibit we've been  
11:12:10 12 talking about, is that correct, DX 1836?

11:12:13 13 A Yes.

11:12:14 14 Q And this particular excerpt is from page 45 of that  
11:12:17 15 document?

11:12:18 16 A Yes.

11:12:18 17 Q Is that correct?

11:12:19 18 In this snapshot Amarin says, "A prespecified" --  
11:12:25 19 well, let me ask you this. This is still talking about the  
11:12:28 20 ACCORD study here, right?

11:12:31 21 A Yes, this is the ACCORD study.

11:12:33 22 Q In this particular snapshot Amarin says,

11:12:35 23 "A prespecified subgroup analysis of subjects  
11:12:38 24 with both high baseline triglycerides, greater than,  
11:12:41 25 204 and low baseline HDL-C, less than or equal to 34,

11:12:47 1 suggested a benefit to fenofibrate therapy in this  
11:12:50 2 subgroup with a 31 percent reduction in the primary  
11:12:54 3 endpoint (P equals 0.057 for the interaction)."

11:13:00 4 The subgroup here, this is a subgroup from the  
11:13:05 5 ACCORD study, correct?

11:13:06 6 A Yes.

11:13:06 7 Q And why was Amarin focusing the FDA on the fact that the  
11:13:12 8 subgroup that's described in the statement in the ACCORD study  
11:13:15 9 actually showed a positive cardiac benefit from treatment with  
11:13:23 10 fenofibrate and statin?

11:13:24 11 A Because these were the lipid levels that were included in  
11:13:27 12 the patients in the ANCHOR and REDUCE-IT study. So this most  
11:13:36 13 resembled the patients within the ACCORD study that had this  
11:13:41 14 lipid profile that demonstrated the benefit of fenofibrate  
11:13:49 15 therapy. Their characteristics resembled patients in the  
11:13:53 16 ANCHOR and REDUCE-IT study.

11:13:55 17 Q And did you compare the lipid profile of the ACCORD  
11:13:58 18 subgroup that Amarin mentions in this statement to the lipid  
11:14:02 19 profile in patients reviewed in the REDUCE-IT study?

11:14:04 20 A Yes, I did.

11:14:05 21 MS. HUTTNER: Can I show you DDX 9.84, please.

11:14:05 22 BY MS. HUTTNER:

11:14:09 23 Q Is this the comparison you made?

11:14:11 24 A Yes.

11:14:11 25 Q And what did -- how do they compare, the ACCORD subgroup

1 that Amarin was focusing on and the REDUCE-IT population?

2 A So, we've already gone over the ACCORD subgroup data, but  
3 we then go to the right column and look at the comparable  
4 values for triglycerides and HDL cholesterol, and we see that  
5 these patients in the ACCORD subgroup would be accommodated in  
6 the REDUCE-IT population as well. They would be included in  
7 the REDUCE-IT population.

8 Q In your opinion, Dr. Fisher, were Amarin's arguments to  
9 FDA about the ACCORD study consistent with Dr. Ismail's  
10 suggestion that based on the failure of that study to show  
11 overall cardiac benefit that one would not have predicted the  
12 outcome in REDUCE-IT?

13 A No, they are not consistent with Dr. Ismail's statement.

14 Q Okay. Let's move on to the ASCEND study which is another  
15 study Dr. Ismail characterized as a failure. First of all,  
16 what was the ASCEND study?

17 A That was another study in diabetics, in this case,  
18 looking at two treatments, either single or in combination,  
19 low-dose aspirin versus low-dose or 1 gram of Lovaza on  
20 cardiovascular endpoints.

21 Q And have you seen any public discussion by Amarin about  
22 the ASCEND study?

23 A Yes, I have.

24 MS. HUTTNER: Can we have DDX 9.94, please.

25

11:15:42 1 BY MS. HUTTNER:

11:15:49 2 Q Okay. And, again, just for the record in the background  
11:15:51 3 is the source document which is DX 2142, and the snapshots are  
11:15:56 4 taken from pages 1 and 2 of that document.

11:15:59 5 Focusing on DX 2142, is this one of the documents  
11:16:03 6 that you relied on in your expert report?

11:16:05 7 A It is.

11:16:05 8 Q And did you obtain this document from Amarin's website?

11:16:09 9 A Yes.

11:16:11 10 MS. HUTTNER: Your Honor, we would move DX 2142  
11:16:14 11 into evidence.

11:16:15 12 MR. SIPES: No objection, Your Honor.

11:16:15 13 THE COURT: 2142 is admitted.

11:16:15 14 (Defendant's Exhibit 2142 received in  
11:16:15 15 evidence.)

11:16:15 15 BY MS. HUTTNER:

11:16:20 16 Q Okay. Now, in DDX 9.94 you have a couple of statements  
11:16:24 17 that you've pulled out of this Web publication, and just in  
11:16:28 18 general, what was Amarin talking about here?

11:16:31 19 A Well, the differences between ASCEND and REDUCE-IT that  
11:16:38 20 would essentially make the result of the ASCEND trial not  
11:16:48 21 relevant to the REDUCE-IT study.

11:16:53 22 Q All right. In the second call-out on DDX 9.94, Amarin  
11:16:59 23 says,

11:16:59 24 "Amarin believes that these differences in  
11:17:01 25 study drug, design, and execution clearly

11:17:06 1 differentiate REDUCE-IT from the ASCEND clinical  
11:17:09 2 trial," correct?

11:17:11 3 A That is correct.

11:17:11 4 Q And the differences that they're talking about in study  
11:17:16 5 drug, design, and execution, does DX 2142 say what those  
11:17:23 6 differences are?

11:17:23 7 A Yes, they do.

11:17:25 8 MS. HUTTNER: And, actually, if we can just call  
11:17:27 9 up DDX 9.29, please.

11:17:27 10 BY MS. HUTTNER:

11:17:32 11 Q This chart is a chart that was part of DX 2142 at page 2?

11:17:40 12 A Yes.

11:17:41 13 Q So in other words this -- the chart in DDX 9.29 is  
11:17:46 14 something you took from DX 2142 without the highlighting,  
11:17:51 15 right?

11:17:51 16 A Yes.

11:17:51 17 Q Okay. And what is the purpose of this chart? What is  
11:17:55 18 Amarin showing here?

11:17:56 19 A The differences between the two studies, which would  
11:17:59 20 argue that the failure in ASCEND to achieve a positive  
11:18:05 21 endpoint is not relevant, would not be predictive of what's  
11:18:09 22 going on with the REDUCE-IT trial.

11:18:12 23 Q And what were the differences that they focused on?

11:18:14 24 A Well, so highlighted we see the patient populations are  
11:18:18 25 different in REDUCE-IT. They're statin-treated so they have

11:18:22 1 to be statin-treated.

11:18:24 2 And they have high CV risk, a high percentage were  
11:18:28 3 in the secondary prevention group. That means they already  
11:18:32 4 had documented cardiovascular disease, and their triglycerides  
11:18:36 5 were in the high range, 150 to 499.

11:18:39 6 In the ASCEND, the patients had diabetes without  
11:18:43 7 evidence of cardiovascular disease, and then, in terms of  
11:18:47 8 statin-therapy, as I mentioned already, but just to repeat,  
11:18:53 9 that statin use was mandated for all patients, and in the  
11:18:56 10 ASCEND statin use was not mandated.

11:18:59 11 And the results, again, the difference between hard  
11:19:03 12 and soft endpoints in REDUCE-IT, these are hard endpoints that  
11:19:08 13 are monitored and adjudicated by experts, where in the ASCEND  
11:19:12 14 study, the events were self-reported by questionnaires that  
11:19:18 15 the patients filled out.

11:19:20 16 Q And we don't have it highlighted, but is there a  
11:19:23 17 difference in the doses of fish oil products that were used in  
11:19:27 18 those two studies?

11:19:28 19 A Yes, in the REDUCE-IT it's Vascepa pure EPA of 4 grams  
11:19:32 20 per day, and there are two notable differences in ASCEND, it's  
11:19:36 21 not only a mixture of EPA and DHA, of Omacor which then became  
11:19:42 22 the name Lovaza, Lovaisa, Lovaza, and that was at 1 gram a day  
11:19:49 23 as opposed to 4 grams a day.

11:19:52 24 Q And is there another portion --

11:19:54 25 MS. HUTTNER: Let's go to DDX 9.93.

11:19:54 1 BY MS. HUTTNER:

11:19:59 2 Q This again is from an excerpt from the Web publication  
11:20:04 3 DX 2142?

11:20:06 4 A Yes.

11:20:06 5 Q From Amarin's website?

11:20:08 6 A Yes.

11:20:08 7 Q In this snapshot on DDX 9.93, Amarin says,

11:20:13 8 "As the article published in JAMA titled  
11:20:16 9 'Associations of omega-3 Fatty Acids Supplement Use  
11:20:22 10 With Cardiovascular Disease Risks Reported,' most of  
11:20:25 11 the studies included in this meta-analysis concerned  
11:20:28 12 mixed EPA and DHA omega-3 products administered daily  
11:20:34 13 at a low dose and were not positive. The only trial  
11:20:37 14 conducted were a different drug and dose level was  
11:20:37 15 the JELIS trial which showed a statistically  
11:20:40 16 significant positive result."

11:20:43 17 Can you just explain what the JAMA article that  
11:20:47 18 Amarin is referring to here?

11:20:50 19 A Well, a meta-analysis -- meta-analysis means that in this  
11:20:56 20 article a number of studies were analyzed to see what the  
11:21:03 21 general pattern of results would be so that -- no single study  
11:21:09 22 is necessarily definitive, so frequently meta-analysis experts  
11:21:15 23 will take a step back and take into account the results from a  
11:21:20 24 variety of studies.

11:21:22 25 Q Okay. And what was -- what point do you understand

11:21:25 1 Amarin to be making in this snapshot?

11:21:28 2 A So that when there's a meta-analysis of studies in which  
11:21:31 3 mixed EPA and DHA omega-3 products were given at a low dose,  
11:21:41 4 as we just went over in ASCEND, they were not positive.

11:21:47 5 And then drawing a sharp distinction between those  
11:21:51 6 studies and the only trial conducted with a different drug and  
11:21:57 7 dose level was the JELIS trial which showed a statistically  
11:22:00 8 significant positive result.

11:22:01 9 And they point out that this was the trial in which  
11:22:05 10 pure EPA was used and which resulted in a demonstrated  
11:22:11 11 relative risk reduction of 19 percent on top of statin therapy  
11:22:17 12 compared to statin therapy alone.

11:22:19 13 Q In your opinion, Dr. Fisher, were Amarin's remarks on its  
11:22:23 14 website about the ASCEND trial consistent with Dr. Ismail's  
11:22:29 15 suggestion that because the ASCEND trial was not -- was -- did  
11:22:33 16 not show a positive result, that therefore that persons of  
11:22:41 17 ordinary skill in the art would also expect the REDUCE-IT  
11:22:43 18 study to fail?

11:22:44 19 A No, this is not consistent with Dr. Ismail's criticism.

11:22:50 20 Q Let's move on to the FIELD study, which is another one of  
11:22:56 21 the studies that Dr. Ismail characterizes as a failed study in  
11:23:01 22 his report, correct?

11:23:02 23 A Yes.

11:23:03 24 MS. HUTTNER: Let's have DDX 9.31.

11:23:03 25

11:23:03 1 BY MS. HUTTNER:

11:23:09 2 Q Okay. And on DDX 9.31, on the left, we have the  
11:23:14 3 underlying source document which is DX 2126, and on the right  
11:23:22 4 we have an excerpt from page 9 from DX 2126. So let's start  
11:23:29 5 with DX 2126, and can you identify that exhibit for the  
11:23:33 6 record, sir?

11:23:34 7 A Yes. This is an article after both the ACCORD and FIELD  
11:23:41 8 studies were reported looking at the implications of those  
11:23:46 9 studies for the treatment of dyslipidemia in Type 2 diabetes  
11:23:54 10 mellitus.

11:23:54 11 Q Okay. And on left-hand side of DX 2121 there's name,  
11:23:59 12 Marshall Elam. Is he is the lead author of this article?

11:24:07 13 A Yes, he's the first author.

11:24:07 14 Q Okay. Now, in this article -- the article is called the  
11:24:10 15 ACCORD Lipid Only, and it goes with a few more words I can't  
11:24:14 16 read right now, but did this article actually discuss the  
11:24:18 17 FIELD study as well as the ACCORD study?

11:24:20 18 A Yes.

11:24:21 19 MS. HUTTNER: Your Honor, I would move DX 2126  
11:24:24 20 into evidence.

11:24:25 21 MR. SIPES: No objection, Your Honor.

11:24:25 22 THE COURT: 2126 is at admitted.

11:24:25 23 (Defendant's Exhibit 2126 received in  
11:24:25 evidence.)

11:24:25 24 BY MS. HUTTNER:

11:24:30 25 Q In the first highlighted portion Dr. Elam discusses the

11:24:33 1 FIELD study, correct?

11:24:34 2 A Yes.

11:24:34 3 Q What is his description of the FIELD study?

11:24:37 4 A That it was a placebo-controlled mixed primary and  
11:24:42 5 secondary prevention trial which meant it had patients in both  
11:24:46 6 primary and secondary prevention groups, using fenofibrate in  
11:24:53 7 9,795 patients with Type 2 diabetes mellitus and it was  
11:24:58 8 conducted in Australia, Finland, and New Zealand.

11:25:06 9 Q In the FIELD study, the overall study did not a positive  
11:25:12 10 outcome; is that correct?

11:25:13 11 A That is correct?

11:25:13 12 Q In the last highlighted sentence on the snapshot on  
11:25:17 13 DDX 9.31, Amarin -- I'm sorry, Dr. Elam says,

11:25:21 14 "In subsequent *post hoc* analyses of the  
11:25:25 15 influence of various components of the metabolic  
11:25:29 16 syndrome on CHD outcomes in FIELD, a subset  
11:25:32 17 (21 percent) of participants with the baseline  
11:25:35 18 characteristics of combined low HDL-C levels of less  
11:25:38 19 than 1.04 millimoles per liter in men and less than  
11:25:42 20 1.3 millimoles per liter in women (which equates to  
11:25:46 21 less than 40 and less than 50 milligrams per  
11:25:49 22 deciliter respectively) and hypertriglyceridemia  
11:25:51 23 experienced 27 percent fewer cardiovascular events  
11:25:55 24 with fenofibrate treatment."

11:25:59 25 So what is Dr. Elam pointing out there?

11:26:04 1 A Well, first, higher up, it's not highlighted, but he does  
11:26:08 2 say among previous fibrate trials, FIELD is most similar to  
11:26:14 3 ACCORD lipid.

11:26:14 4 And as we reviewed in ACCORD lipid, when you look at  
11:26:17 5 the subgroup with elevated triglycerides and low HDL, there  
11:26:21 6 was a significant effect.

11:26:22 7 And he's making the same point here in FIELD that if  
11:26:25 8 we separately analyze those subjects in FIELD that had these  
11:26:30 9 lipoprotein characteristics of elevated triglycerides and low  
11:26:36 10 HDL, in this case using gender specific cutoff points, there  
11:26:41 11 was a significant reduction, 27 percent reduction in  
11:26:46 12 cardiovascular events with fenofibrate treatment.

11:26:49 13 Q And have you compared the lipid profiles of the patients  
11:26:55 14 that Dr. Elam was discussing in this last highlighted portion  
11:27:02 15 with the lipid profile patients enrolled in the REDUCE-IT  
11:27:04 16 study?

11:27:05 17 A Yes.

11:27:05 18 Q Can I show you DDX 9.32?

11:27:08 19 A Yes.

11:27:09 20 Q Is this the chart that you prepared?

11:27:11 21 A Yes, it is.

11:27:11 22 Q And how do the lipid profiles of the patients that  
11:27:18 23 Dr. Elam commented on in the FIELD study, how do they compare  
11:27:22 24 to the patients in REDUCE-IT?

11:27:24 25 A Well, we already went over the FIELD results, and just

1 comparing them now to REDUCE-IT, we see both in terms of the  
2 triglycerides and the HDL-C, these characteristics are very  
3 similar to what is in the REDUCE-IT trial.

4 The median baseline HDL cholesterol in REDUCE-IT of  
5 40 milligrams per deciliter is considered low whether it's a  
6 man or a woman. So it basically means the same thing in both  
7 studies, that the baseline HDL was on the low side and the  
8 triglycerides were elevated.

9 Q All right. Let's talk about the last study that  
10 Dr. Ismail discusses, or the last study that he characterized  
11 as a failed study, and that's the ORIGIN study.

12 What was the ORIGIN study about?

13 A So that was another study in diabetics and looking at two  
14 different factors in terms of cardiovascular risk. The two  
15 factors was that use of a particular insulin called Glargine,  
16 and the fish oil that was tested was, again, a 1 gram dose of  
17 Lovaza.

18 Q And how -- did the participants in the ORIGIN study have  
19 elevated triglycerides?

20 A No, they did not. They actually had a normal level of  
21 triglycerides and their HDL levels were also normal.

22 Q What about their LDL-C levels, were they also normal?

23 A Yes.

24 Q And would you expect to see -- in a cardiac outcomes  
25 trial, would you expect it to be able to detect a reduction in

11:29:09 1 cardiac risk -- in cardiac risk in patients with essentially  
11:29:14 2 normal lipid levels?

11:29:16 3 A No, these would be considered to be low risk population.

11:29:21 4 Q And do you view the -- the negative outcome of the ORIGIN  
11:29:26 5 study, do you view that as predictive of what would happen in  
11:29:29 6 REDUCE-IT which was in a population of patients with elevated  
11:29:33 7 triglycerides and low HDL-C and mildly elevated LDL-C?

11:29:39 8 A No. There are obvious differences in the patient  
11:29:43 9 characteristics as well as, again, the dose and the type of  
11:29:47 10 fish oil that was used.

11:29:49 11 Q In your opinion, would a POSA have viewed the negative  
11:29:49 12 outcome of the ORIGIN study as an indication that Vascepa  
11:29:49 13 would also fail to show a cardiac benefit in REDUCE-IT?

11:29:59 14 A I don't think a person of ordinary skill would have come  
11:30:03 15 to that conclusion based on that study.

11:30:05 16 Q Do you think it's fair to compare the ORIGIN study to  
11:30:09 17 REDUCE-IT?

11:30:09 18 A No, it's not fair.

11:30:10 19 Q All right. Let's move on to Dr. Mason's opinions. You  
11:30:14 20 also reviewed Dr. Mason's reports in this case, right?

11:30:17 21 A I did.

11:30:17 22 Q And Dr. Mason summarized his opinions in his opening  
11:30:21 23 expert report in this case?

11:30:23 24 A He did.

11:30:24 25 MS. HUTTNER: Can we have DDX 9.35, please.

11:30:24 1 BY MS. HUTTNER:

11:30:29 2 Q DDX 9.35 is a blowup of paragraph 5 from Dr. Mason's  
11:30:35 3 opening report, correct?

11:30:36 4 A Yes.

11:30:36 5 Q And in paragraph 5, Dr. Mason set -- summarized the  
11:30:42 6 opinions that he plans to testify to in this case, correct?

11:30:44 7 A Yes.

11:30:45 8 Q And let's start with Dr. Mason's opinions.

11:30:54 9 His first opinion, he says,

11:30:55 10 "In this report, I offer my opinion that  
11:30:58 11 administration of Vascepa as described in the  
11:31:01 12 asserted claims is unexpectedly associated with the  
11:31:04 13 following beneficial physiological effects."

11:31:07 14 And then he goes on to list those physiological  
11:31:10 15 effects as stabilization of membrane, improvement of  
11:31:16 16 endothelial functions, stabilization and/or regression of  
11:31:19 17 plaque, and anti-inflammatory effects including a reduction of  
11:31:22 18 high sensitivity C reactive protein.

11:31:25 19 And then he continues, he says,

11:31:28 20 "In my opinion, these physiological effects  
11:31:31 21 are likely responsible for Vascepa's unexpected  
11:31:34 22 reduction in cardiovascular risks." And then he says  
11:31:37 23 "In addition, those effects would likely apply to  
11:31:39 24 patients with triglyceride levels above or equal to  
11:31:43 25 greater than 500, and there is a strong basis to

11:31:46 1 conclude that the cardiovascular risk reduction with  
11:31:48 2 Vascepa observed in a clinical trial called REDUCE-IT  
11:31:51 3 applies to patients with triglyceride levels above  
11:31:55 4 500."

11:31:56 5 Does that paragraph, as far as you're aware,  
11:31:59 6 accurately set forth Dr. Mason's opinions in this case?

11:32:02 7 A Yes.

11:32:08 8 Q All right. Let's start with Dr. Mason's opinion that the  
11:32:11 9 four physiological benefits that he identifies in paragraph 5,  
11:32:17 10 and to use his words, are "likely responsible" for the  
11:32:19 11 reduction in cardiac risk shown in REDUCE-IT.

11:32:23 12 First of all, do you agree with Dr. Mason's opinion?

11:32:25 13 A No.

11:32:34 14 Q Why not?

11:32:35 15 A Because, as the Bhatt article points out, that the  
11:32:39 16 mechanism for the effects of EPA are unknown.

11:32:43 17 MS. HUTTNER: Let's go to the Bhatt article.  
11:32:47 18 Can I have DDX 9.36, please.

11:32:47 19 BY MS. HUTTNER:

11:32:53 20 Q This is what you were referring to in your prior answer,  
11:32:56 21 Dr. Fisher?

11:32:56 22 A Yes.

11:32:57 23 Q All right. So this is PX 272 at page 10 which is the  
11:32:57 24 Bhatt article announcing the REDUCE-IT study results.

11:33:03 25 And Dr. Bhatt says in the snapshot,

11:33:07 1 "Mechanisms responsible for the benefit of  
11:33:09 2 icosapent ethyl observed in REDUCE-IT are currently  
11:33:12 3 not known."

11:33:13 4 Does that statement square with Dr. Mason's  
11:33:19 5 opinion that the mechanisms he identifies are the likely cause  
11:33:24 6 of the cardiac benefits in REDUCE-IT?

11:33:27 7 A No, it's inconsistent with his statement.

11:33:31 8 MS. HUTTNER: If we can go now to DDX 9.45.

11:33:37 9 DDX 9.45 is an excerpt from the clinical  
11:33:43 10 pharmacology section of PX 1186, which I believe is in  
11:33:50 11 evidence, Your Honor. This is the current Vascepa label with  
11:33:53 12 the additional cardiac indication.

11:33:55 13 THE COURT: Yes, it is.

11:33:55 14 BY MS. HUTTNER:

11:33:57 15 Q Dr. Fisher, what -- under the heading Clinical  
11:34:00 16 Pharmacology, there's a subheading that says Mechanism of  
11:34:05 17 Action. What is your understanding of what Amarin is doing in  
11:34:07 18 this section?

11:34:08 19 A Well, they're trying to explain how EPA does what it does  
11:34:15 20 at a cellular level.

11:34:17 21 Q And, to your understanding, does the FDA require drug  
11:34:21 22 manufactures to disclose whatever they know about the  
11:34:24 23 mechanism of action of drugs that they're selling?

11:34:26 24 A Yes.

11:34:27 25 Q So is it your expectation that is Amarin's best

11:34:30 1 understanding of how Vascepa works to provide cardiac  
11:34:33 2 benefits?

11:34:33 3 A Yes, it is.

11:34:34 4 Q And Amarin, in the snapshot from section 12.1 of their  
11:34:39 5 current label, says,

11:34:40 6 "The mechanisms of action contributing to  
11:34:43 7 reduction of cardiovascular events with Vascepa  
11:34:46 8 (icosapent ethyl) are not completely understood but  
11:34:50 9 are likely multifactorial."

11:34:51 10 What does that mean?

11:34:53 11 A Well, not completely understood is just plain English  
11:34:58 12 that they don't know, and -- but whatever they are, it's  
11:35:06 13 likely to involve a number of mechanisms working in  
11:35:12 14 combination.

11:35:13 15 Q Now, in section 12.1 the of Vascepa label, Amarin also --  
11:35:18 16 at the very beginning talks about some of the things that  
11:35:23 17 studies suggest that EPA can do, right?

11:35:25 18 A Yes.

11:35:26 19 Q And does Amarin, either there or anywhere else in the  
11:35:31 20 clinical pharmacology section, does it refer to any of the  
11:35:36 21 physiological benefits that Dr. Mason identifies in paragraph  
11:35:40 22 5 of his report?

11:35:41 23 A No.

11:35:42 24 Q In the last highlighted sentence on this exhibit, Amarin  
11:35:48 25 says,

11:35:49 1 "However, the direct clinical meaning of  
11:35:52 2 individual findings is not clear."

11:35:54 3 What do you understand that to be referring to?

11:35:57 4 A Well, for the mechanisms that they propose here, or list  
11:36:05 5 here, that even though there might be evidence from typically  
11:36:11 6 preclinical models, that has not been demonstrated to actually  
11:36:16 7 be operating in a living patient. That's what's meant by the  
11:36:22 8 direct clinical meaning of any one of those findings is not  
11:36:26 9 clear.

11:36:26 10 Q And would the same be true of -- assuming that they are  
11:36:32 11 physiological properties of EPA, would the same be true of the  
11:36:36 12 four physiological properties that Dr. Mason identifies in his  
11:36:40 13 report?

11:36:40 14 A Yes, it would be the same.

11:36:42 15 Q Now, does the Bhatt paper --

11:36:50 16 MS. HUTTNER: Let's go back to DDX 9.36.

11:36:50 17 BY MS. HUTTNER:

11:36:57 18 Q Okay. So, again, we're talking -- just to orient  
11:37:00 19 ourselves, we're talking -- the excerpt on the screen is from  
11:37:03 20 the Bhatt paper which is in evidence, correct?

11:37:05 21 A Yes.

11:37:05 22 Q And in this -- well, let me just ask you this. Does the  
11:37:12 23 Bhatt paper about REDUCE-IT, does it discuss -- discuss the  
11:37:22 24 issue of whether the use of Vascepa to lower triglycerides, in  
11:37:26 25 other words, the methods recited in the claims, does it

11:37:28 1 discuss whether or not practicing those methods is what's  
11:37:32 2 producing the cardiac benefits in Vascepa?

11:37:37 3 A Could you rephrase that?

11:37:38 4 Q Yeah. Does Dr. Bhatt in this article indicate that there  
11:37:42 5 is a connection between the method of lowering triglycerides  
11:37:46 6 that's described in the patents in this case and the cardiac  
11:37:50 7 benefits that were shown in REDUCE-IT?

11:37:52 8 A No.

11:37:53 9 Q Well, let me direct your attention to --

11:37:57 10 MS. HUTTNER: Let's go to DDX 9.44.

11:37:57 11 BY MS. HUTTNER:

11:38:02 12 Q These -- DDX 9.44 has an excerpt on the left from page 7  
11:38:07 13 of the Bhatt article, right?

11:38:09 14 A Yes.

11:38:10 15 Q And on the right it's from page 10 of the Bhatt article,  
11:38:14 16 correct?

11:38:14 17 A Yes.

11:38:14 18 Q In these sections of the Bhatt article, is Dr. Bhatt  
11:38:19 19 discussing the relationship between triglyceride levels and  
11:38:23 20 the cardiac outcomes observed in the REDUCE-IT study?

11:38:27 21 A Yes, he is.

11:38:28 22 Q And what does he say here. Let's start with the one --  
11:38:30 23 with the excerpt from page 7 on the left.

11:38:32 24 A Well, he's saying that the baseline triglyceride levels,  
11:38:37 25 and he divides them into two, two groups, those with less than

11:38:43 1 150 milligrams per deciliter versus equal or greater than 150,  
11:38:51 2 or, if you use the cut point of 200, so it would be less than  
11:38:54 3 200 versus equal or greater than 200, these baseline trigly --  
11:39:04 4 I can't even pronounce it any more -- triglyceride levels had  
11:39:05 5 no difference on the primary or key secondary efficiency  
11:39:11 6 endpoints -- efficacy, sorry, efficacy endpoints.

11:39:13 7 Q And if we can go to the excerpt on the right, please,  
11:39:18 8 which is from page 10 of the Bhatt article, what is Dr. Bhatt  
11:39:26 9 saying here?

11:39:26 10 A Well, he repeats the first -- the gist of what I just  
11:39:30 11 discussed about the observed cardiovascular benefits were  
11:39:33 12 similar across the baseline levels of triglycerides, but then  
11:39:37 13 extends this to the treatment, on treatment levels at one  
11:39:43 14 year.

11:39:43 15 So the significantly lower risk of major adverse  
11:39:50 16 cardiovascular events with icosapent ethyl than with placebo  
11:39:55 17 appeared to occur irrespective with the attained triglyceride  
11:40:00 18 level at one year using the 150 cut point in this excerpt,  
11:40:06 19 less than 150 or greater than or equal to 150 per deciliter.

11:40:12 20 And he concludes that this suggests that the  
11:40:14 21 cardiovascular risk reduction was not associated with  
11:40:17 22 attainment of a more normal triglyceride level.

11:40:20 23 Q So, in effect, in these two statements that we've looked  
11:40:24 24 at from the Bhatt article, is Dr. Bhatt saying that there was  
11:40:27 25 no evidence that the cardiac benefits observed in REDUCE-IT

1 resulted from the lowering of triglycerides by Vascepa?

2 A That is what he's saying.

3 Q And does Dr. Bhatt also discuss the question of whether  
4 there is any relationship between the fact that LDL-C does not  
5 raise -- I'm sorry, that Vascepa does not raise LDL-C levels  
6 in the results, the cardiac benefits shown in the REDUCE-IT  
7 study?

8 A He does discuss that.

9 MS. HUTTNER: Can we go to DDX 9.42, please.

10 BY MS. HUTTNER:

11 Q DDX 9.42 was, again, an excerpt from PX 272. This  
12 excerpt is from page 7, correct?

13 A Yes.

14 Q And, in this excerpt, is Dr. Bhatt discussing the  
15 relationship, if any, between LDL cholesterol levels and the  
16 cardiac benefits shown in REDUCE-IT?

17 A Yes, he is.

18 Q What does he say about that subject?

19 A "In a post hoc analysis we found no  
20 substantial difference in the benefit of icosapent  
21 ethyl as compared with placebo with respect to the  
22 primary endpoint according to whether the patients  
23 who received placebo had an increase in LDL  
24 cholesterol levels at one year or had no change or  
25 a decrease," even a decrease in LDL cholesterol levels.

11:42:06 1 So there was no relationship to the LDL cholesterol  
11:42:09 2 levels at one year, the one year time point.

11:42:14 3 Q So is this basically saying that the fact that Vascepa  
11:42:18 4 lowers triglycerides without raising LDL-C had nothing to do  
11:42:23 5 with the outcome in REDUCE-IT?

11:42:23 6 A Yes.

11:42:26 7 Q Cardiac benefits?

11:42:27 8 A Yes.

11:42:27 9 Q And did you also look at the clinical study report for  
11:42:31 10 REDUCE-IT which is PX 271?

11:42:34 11 A I did.

11:42:35 12 MS. HUTTNER: And, Mr. Gross, can you bring up  
11:42:39 13 PX 271.

11:42:42 14 And, Your Honor, I know there was clinical study  
11:42:44 15 report that was admitted into evidence, but I -- I'm not sure  
11:42:48 16 if there was more than one document that's called that.

11:42:51 17 So I don't know if PX 271 is in evidence, but in  
11:42:55 18 a moment when I lay foundation, I'll ask that it be moved into  
11:42:58 19 evidence.

11:42:58 20 THE COURT: Is this the REDUCE-IT clinical  
11:42:58 21 report --

11:42:58 22 MS. HUTTNER: Yes, Your Honor.

11:43:01 23 THE COURT: This one has been admitted as well.

11:43:03 24 MS. HUTTNER: I'm sorry?

11:43:03 25 THE COURT: Well --

11:43:05 1 MS. HUTTNER: Yes, this is the REDUCE-IT report.

11:43:05 2 THE COURT: I thought the REDUCE-IT report has  
11:43:07 3 been admitted, but is from any objection to its admission?

11:43:10 4 MR. SIPES: We have no objection.

11:43:11 5 THE COURT: All right. If it hasn't been  
11:43:13 6 admitted, it will be, Exhibit --

11:43:16 7 MS. HUTTNER: Thank you, Your Honor.

11:43:17 8 MR. SIPES: And, Your Honor, I would just  
11:43:18 9 reiterate the concern we expressed at the beginning that we  
11:43:19 10 have time for redactions before these exhibits are published.

11:43:23 11 THE COURT: Yes.

11:43:23 12 (Plaintiff's Exhibit 271 received in  
11:43:23 13 evidence.)

11:43:23 13 BY MS. HUTTNER:

11:43:27 14 Q Okay. Did the clinical study report for REDUCE-IT,  
11:43:34 15 PX 271, this is a document that you reviewed and relied on in  
11:43:36 16 connection with your opinions in this case?

11:43:38 17 A It is.

11:43:38 18 Q And does the clinical study report for REDUCE-IT, PX 271,  
11:43:44 19 does it discuss the relationship, if any, between apo B being  
11:43:52 20 reduced and the outcome of the REDUCE-IT study, in other  
11:43:57 21 words, the cardiac benefits?

11:44:00 22 A It does.

11:44:01 23 Q And what does it say on that subject?

11:44:03 24 A Well, it's a similar -- as we'll see, it's similar to the  
11:44:07 25 triglycerides and the LDL cholesterol data that the change in

11:44:14 1 apo B were not associated with the reduction in events.

11:44:21 2 MS. HUTTNER: All right. Can we go, Mr. Gross,  
11:44:23 3 to page 186 of PX 271. And can you blow up Figure 11-19.  
11:44:23 4 Thank you.

11:44:23 5 BY MS. HUTTNER:

11:44:35 6 Q What is Figure -- figure 11-19 says it's a forest plot of  
11:44:39 7 analysis of the primary endpoint by subgroups, and one the  
11:44:43 8 subgroups it mentions in the caption is apo B by tertiles?

11:44:48 9 A Yes.

11:44:49 10 Q What is this chart?

11:44:49 11 MR. SIPES: Your Honor, discussion of this chart  
11:44:53 12 is no where in his expert report.

11:44:57 13 MS. HUTTNER: Well, I disagree with that. I  
11:45:00 14 mean, he does discuss the fact that there is no relationship  
11:45:04 15 between the cardiac benefits shown in REDUCE-IT and apo B and  
11:45:10 16 does cite to this document which is a lengthy document.

11:45:14 17 But it was discussed also, I believe, at his  
11:45:16 18 deposition, but I can -- I can do it without the document if  
11:45:20 19 you prefer.

11:45:21 20 MR. SIPES: Your Honor, I'm pretty confident I  
11:45:23 21 did not in fact depose him on this clinical study report. I  
11:45:28 22 don't recall him at all citing to this chart anywhere in his  
11:45:31 23 report.

11:45:31 24 MS. HUTTNER: All right. We can do this without  
11:45:34 25 the chart.

11:45:34 1 BY MS. HUTTNER:

11:45:36 2 Q Did the REDUCE-IT study report, did it find any  
11:45:37 3 relationship between apo B -- lowering apo B and the cardiac  
11:45:39 4 benefits in REDUCE-IT?

11:45:41 5 A It did not.

11:45:44 6 MS. HUTTNER: Okay. So let's move on now to  
11:45:47 7 Dr. Mason's other opinions. Let's go to DDX 9.104 which is  
8 the summary slide we looked at earlier.

9 THE COURT: Can you repeat that?

10 MS. HUTTNER: I'm sorry, 9.104.

11 THE COURT REPORTER: Slow down.

12 MS. HUTTNER: I'm from New York, it's tough.  
13 I'll do my best.

14 THE COURT: I appreciate counsel trying. I  
15 understand how difficult it is. We can only try.

16 MS. HUTTNER: Well, you know, Your Honor, it  
17 sounds like you're talking in slow motion in your head --

18 THE COURT: I know.

19 MS. HUTTNER: And it's hard.

20 THE COURT: I too have to make an intentional  
21 effort to slow down because I tend to talk really fast, too.

22 BY MS. HUTTNER:

11:46:19 23 Q So DDX -- I'm going to say this very slowly. DDX 9.104  
11:46:21 24 is the summary of Dr. Mason's opinions from paragraph 5 of his  
11:46:27 25 opening report that we looked at earlier.

1 And I want to move on now to Dr. Mason's opinion as  
2 stated in paragraph 5 that the administration of Vascepa as  
3 described in the asserted claims is unexpectedly associated  
4 with the four physiologic -- what he calls the beneficial  
5 physiological effects that he identifies in paragraph 5.

6 First of all, do you understand -- when he says that  
7 these physiological effects are unexpectedly associated with  
8 Vascepa, do you understand him to be saying that these -- or  
9 to be expressing the opinion these four physiological effects  
10 were unknown, would not be known to a person -- people of  
11 ordinary skill in the art before 2008?

12 A Yes, that's what I think he is saying.

13 Q And do you agree with him that that is a true statement?

14 A No.

15 Q Before we talk about the reasons for your opinion, I just  
16 want to sort of establish a baseline here in terms of what  
17 your understanding is of what Dr. Mason is talking about in  
18 relationship to each of these physiological effects.

19 So let's start with stabilization of membrane. What  
20 is your understanding of what Dr. Mason means by that?

21 A Well, he uses this in the context of two types of cells  
22 that are in atherosclerotic plaques, the endothelial cells and  
23 macrophages, and all cells have membranes, they have important  
24 functions.

25 And that stabilization of membrane I have understood

11:48:08 1 him to mean that the proper health of the cell is maintained.  
11:48:16 2 There's protection against damage to the membrane which would  
11:48:20 3 impair the function of either an endothelial cell or a  
11:48:26 4 macrophage cell.

11:48:27 5 Q And how about improvement of endothelial function, what  
11:48:32 6 is your understanding of what Dr. Mason is referring to there?

11:48:35 7 A He mainly discusses the ability of endothelial cells  
11:48:39 8 which line in our arteries, they are the barrier between the  
11:48:43 9 blood flowing through the artery and the tissue in the artery  
11:48:47 10 wall itself, that a major function of those endothelial cells  
11:48:52 11 is to produce nitric oxide which will relax -- will keep the  
11:48:58 12 blood vessel in a relaxed state.

11:49:01 13 And it's known from research through the years that  
11:49:05 14 the ability of NO to maintain what's called the vessel tone in  
11:49:12 15 a relaxed state is a protective feature, and when the vessel  
11:49:17 16 tone is higher, such as in hypertension, this increases the  
11:49:22 17 risk of cardiovascular disease.

11:49:25 18 Q And the third thing, the third physiological function  
11:49:31 19 that Dr. Mason refers to in paragraph 5 is what he calls  
11:49:35 20 stabilization and/or regression of plaque. What does that  
11:49:39 21 mean or what do you understand it to mean?

11:49:41 22 A Well, the common, common use of the term of stabilized  
11:49:48 23 plaque means that this is a plaque, a deposit of cholesterol  
11:49:55 24 inflammatory cells in our coronary arteries that will not  
11:50:01 25 rupture.

1 A heart attack is caused by an unstable plaque which  
2 means that at a certain point there is a breach in the  
3 endothelial cell layer that overlies the plaque and a blood  
4 clot quickly forms which occludes the vessel from supplying  
5 the oxygen to the heart muscle.

6 So that's what a heart attack or myocardial  
7 infarction is thought to result from, the rupture of an  
8 unstable plaque.

9 So on the flip side then stabilization of a plaque  
10 is considered to be a good thing, and that the regression of  
11 the plaque which is actually something I work on in  
12 preclinical models, means that there is a reduced size of the  
13 plaque or a reduced number of inflammatory cells in the plaque  
14 so it becomes less likely to rupture.

15 So a regression of a plaque would also be related to  
16 increasing the stability of that plaque.

17 Q And just so -- you may have said this, and if you did, I  
18 apologize, but just so we're all clear, what is a plaque made  
19 of? I mean what is that?

20 A Well, the central cell of a plaque, as we'll discuss a  
21 little bit today, is the macrophage, and that is a cell that  
22 will gobble up the LDL particles, the apo B containing  
23 lipoprotein particles, and take up the cholesterol from those  
24 particles and become what are called foam cells.

25 It's the accumulation of these foam cells which are

11:51:51 1 filled with cholesterol that cause the plaque to grow and  
11:51:55 2 progress, and eventually, in some individuals, to actually  
11:51:58 3 contribute to this instability and rupture.

11:52:01 4 So a plaque then is a collection of -- in the  
11:52:06 5 simplest sense, a collection of cholesterol filled macrophages  
11:52:11 6 in the wall of the coronary artery.

11:52:15 7 Q All right. Now, the last physiological effect that  
11:52:20 8 Dr. Mason identifies in paragraph 5 is anti-inflammatory  
11:52:28 9 effects including reduction of high sensitivity C reactive  
11:52:28 10 protein hs-CRP.

11:52:31 11 What does that -- what is your understanding of  
11:52:33 12 what he's referring to there?

11:52:35 13 A Well, the inflammation actually is not restricted as --  
11:52:45 14 to just this category because macrophages which I just  
11:52:50 15 explained which are important players in the plaque stability  
11:52:56 16 are inflammatory cells.

11:52:58 17 So what this means is that there would be decreased  
11:53:02 18 inflammation in the cells in a plaque. There would be the  
11:53:07 19 decreased production of small molecules produced by cells that  
11:53:13 20 cause inflammation.

11:53:14 21 And so, in general, anti-inflammatory effects cover  
11:53:20 22 actually very many areas of immunology, but all would be  
11:53:28 23 contributing to a less dangerous state in the plaque if there  
11:53:33 24 was less inflammation.

11:53:35 25 The reduction of high sensitivity C reactive

11:53:39 1 protein, what he's referring to is CRP, is a marker of the  
11:53:45 2 inflammatory state of a plaque. There has been considerable  
11:53:50 3 observational studies that have associated high levels of CRP  
11:53:55 4 with the risk of cardiovascular disease, and it's -- it has  
11:54:02 5 been speculated that when CRP levels go down, there would be  
11:54:08 6 less -- this would reflect there's less inflammation.

11:54:12 7 Q Is CRP the only marker for inflammation?

11:54:17 8 A No, there are many, but that has certainly gotten a lot  
11:54:21 9 of attention.

11:54:22 10 MS. HUTTNER: Okay. Now, let me show you -- if  
11:54:40 11 we can go to DDX 9.117.

11:54:40 12 BY MS. HUTTNER:

11:54:43 13 Q DDX 9.117 is a figure that's from paragraph 46 of  
11:54:47 14 Dr. Mason's opening report; is that correct?

11:54:47 15 A Yes.

11:54:48 16 Q And does this figure tell you anything about whether or  
11:54:54 17 not the four physiological functions identified by Dr. Mason  
11:54:59 18 are distinct or interrelated?

11:55:03 19 A Well, it emphasizes, in my interpretation, about the  
11:55:07 20 interrelatedness because of the convergence of arrows on to  
11:55:12 21 that central cell. The identity of that cell type is not  
11:55:16 22 specified, but based on the material to the left of the cell  
11:55:22 23 where he's talking about adhesion molecules, those are made by  
11:55:27 24 endothelial cells, and macrophage activation, that, of course,  
11:55:32 25 is macrophages, that he is considering that these effects

would be relevant to both endothelial cells and macrophages.

And the things that are in circles that are above the cell would be stimuli, multiple different stimuli, that would serve to increase the inflammatory activity of that cell through a mechanism involving something called the inflannasone, i-n-f-l-a-n-n-a-s-o-n-e, and the output of an inflannasone are these inflammatory molecules that are shown here, interleukin 1 beta and interleukin 6.

We see CRP just at the bottom again as an indicator of the inflammatory state, it's like a readout, it's produced in the liver so it's not direct reflection of the inflammatory state in, say, a plaque itself, but it would be a consequence of cells in the plaque releasing these inflammatory mediators that then would affect other cells in the body.

Q So just to summarize, is it your view that the four functions identified by Dr. Mason in paragraph 5 are all interrelated functions?

A In current understanding, they are all interrelated.

MS. HUTTNER: Now, if we can go back to DDX 9.104, please.

BY MS. HUTTNER:

Q Again, this is the summary paragraph in Dr. Mason's report, but I just want to ask you, the four factors, the four effects that he identifies here, are those effects, as Dr. Mason says, of the administration of Vascepa as described

11:57:37 1 in the asserted claims?

11:57:38 2 A No. They are inherent properties of the compound itself.

11:57:44 3 Q And would the EPA -- and the compound itself being EPA?

11:57:47 4 A Being EPA.

11:57:49 5 Q And would those same effects, assuming that that's an  
11:57:52 6 accurate description of what EPA can do, would those same  
11:57:57 7 effects have been present in the JELIS study?

11:58:01 8 A Yes, I would expect they would be.

11:58:03 9 Q So it has nothing to do with giving 4 grams a day of  
11:58:07 10 Vascepa as opposed to the 1.8 grams of Vascepa given in the  
11:58:10 11 JELIS study?

11:58:11 12 A No. The nature of the effects would be the same. But as  
11:58:16 13 is appreciated, there are dose response considerations so that  
11:58:22 14 there might be at a lower dose less of a response, but  
11:58:27 15 qualitatively the response would be the same.

11:58:30 16 THE COURT: I have -- I have a question. And  
11:58:33 17 Mr. Sipes may be able to explain.

11:58:36 18 The question Ms. Huttner just posed used Vascepa  
11:58:39 19 and EPA in REDUCE-IT interchangeably. Are they  
11:58:43 20 interchangeable?

11:58:44 21 MR. SIPES: The chemical molecules --

11:58:46 22 THE COURT: I mean, there's all -- I'm sorry,  
11:58:48 23 about 96 percent purified EPA.

11:58:51 24 MS. HUTTNER: Your Honor, you may recall that we  
11:58:52 25 looked at a statement by Dr. -- I believe it was by Dr. Bhatt

11:58:59 1 earlier to the FDA Advisory Committee in which he made the  
11:59:04 2 statement -- let me just find it. It's -- I'm sorry,  
11:59:08 3 Dr. Brinton. It's DDX 9.19.

11:59:11 4 THE COURT: Oh, in his in testimony before the  
11:59:11 5 FDA?

11:59:15 6 MS. HUTTNER: Yes. If you look at DDX 9.19, in  
11:59:18 7 that -- in that -- this is before the ad com -- the advisory  
11:59:24 8 committee of the FDA that was considering whether or not to  
11:59:25 9 continue the special protocol assessment agreement.

11:59:28 10 And he says explicitly, "Does Vascepa actually  
11:59:31 11 equal Epadel," and he goes on to say that they're both greater  
11:59:35 12 than 98 percent EPA and that there's no known chemical  
11:59:38 13 difference between the two, and there are other documents in  
11:59:40 14 the production that say essentially the same thing.

11:59:44 15 THE COURT: And it's not really relevant --

11:59:45 16 MS. HUTTNER: No, I believe the only  
11:59:47 17 difference --

11:59:47 18 THE COURT: -- material to the final issues in  
11:59:48 19 the case, but I was just curious.

11:59:48 20 MS. HUTTNER: Yeah, the only --

11:59:51 21 MR. SIPES: Yes -- excuse me.

11:59:51 22 THE COURT: I'll let Ms. Huttner finish and then  
11:59:54 23 you can -- I'll let you --

11:59:54 24 MS. HUTTNER: I mean, to be completely candid,  
11:59:55 25 the only thing I've seen in the various documents I've looked

1 at in this case in regards to any difference between EPA and  
2 the Epadel product and EPA and the Vascepa product is that  
3 apparently they have a slightly different, you know, impurity  
4 profile.

5 So, you know, they have certain trace amounts of  
6 things in them, but that's the only difference I'm aware of.

7 MR. SIPES: To unpack the statement that  
8 Ms. Huttner pointed to from Dr. Brinton, he said they both  
9 contain pure EPA ethyl ester, there's no known chemical  
10 difference between the two, that is, they both contain the  
11 same molecule, this EPA molecule.

12 There may be other trace amounts of other  
13 omega-3s, or other things that in there, but they both contain  
14 the same EPA molecule.

15 THE COURT: I think that's the same as what  
16 Ms. Huttner just explained.

17 MS. HUTTNER: It is, Your Honor.

18 THE COURT: Thank you.

19 MS. HUTTNER: I'm sorry, Your Honor, just bear  
20 with me while I find my way back to --

21 THE COURT: I apologize.

22 MS. HUTTNER: No, no, don't apologize. It's  
23 totally fine. I would rather you had your questions answered.

24 THE WITNESS: I was hoping you'd want to hear  
25 more about macrophages.

12:01:02 1 MS. HUTTNER: We can have a private conversation  
12:01:06 2 later, Dr. Fisher.

12:01:06 3 THE WITNESS: Professors like to profess.

12:01:06 4 BY MS. HUTTNER:

12:01:10 5 Q Okay. So I think we were -- I think I had just asked you  
12:01:14 6 whether the effects of EPA that Dr. Mason identifies in his  
12:01:20 7 report, whether those were effects of the method of  
12:01:25 8 administration or of the molecule itself, and your answer was  
12:01:29 9 again?

12:01:30 10 A The molecule itself.

12:01:33 11 Q Okay. Now, are any of the -- the four functions that  
12:01:46 12 Dr. Mason identifies in paragraph 5, in your opinion, were  
12:01:50 13 those four functions, as he says, unexpected in 2008?

12:01:55 14 A No.

12:01:55 15 Q Were they known?

12:01:56 16 A They were known.

12:01:59 17 Q And you have a slide -- and you discussed this in your  
12:02:01 18 report and you relied on certain references, correct?

12:02:04 19 A Yes, I did.

12:02:05 20 Q And you have a slide that discusses those -- that depicts  
12:02:08 21 those references, so let's look at DDX 9.40.

12:02:18 22 Okay. And in this slide, you list the physiological  
12:02:23 23 effect identified by Dr. Mason on the left and the references  
12:02:28 24 in the prior art that you're relying on where you believe  
12:02:31 25 those same functions are disclosed; is that right?

12:02:34 1 A Yes.

12:02:35 2 Q And the references you list are Yokoyama, Suzuki, Omura,  
12:02:43 3 Terano, Surette, and I think that covers them all, correct?

12:02:48 4 A Yes.

12:02:48 5 Q And you list some of these references in multiple  
12:02:51 6 categories, correct?

12:02:52 7 A I do.

12:02:52 8 Q The first -- let's talk about the references that you  
12:02:56 9 list and why you believe that they disclose the functions  
12:03:01 10 identified by Dr. Mason.

12:03:03 11 And just so I don't have to keep saying it, all  
12:03:06 12 these references that you rely on were published before 2008,  
12:03:09 13 correct?

12:03:09 14 A Correct.

12:03:09 15 Q Now, the first article you list in your chart is  
12:03:15 16 Yokoyama, and, again, this is the article about the JELIS  
12:03:18 17 study that has been admitted into evidence in this case as  
12:03:22 18 DX 1553, correct?

12:03:23 19 A Yes.

12:03:24 20 Q And we talked about that earlier in your testimony, and  
12:03:26 21 it's come up -- figures large in this case as well, right?

12:03:29 22 A Yes.

12:03:32 23 Q I want to direct your attention to -- if we can go to  
12:03:36 24 DDX 9.118. There is -- is there disclosure in Yokoyama of the  
12:03:42 25 biological functions of EPA, the known biological functions of

12:03:47 1 EPA?

12:03:48 2 A Yes, there is.

12:03:48 3 Q And in DDX 9.118, have you reproduced that disclosure?

12:03:54 4 A I have.

12:03:54 5 Q And this is from page 1 of Yokoyama, correct?

12:03:57 6 A Yes.

12:03:58 7 Q And it says,

12:03:59 8 "The biological functions of EPA include  
12:04:02 9 reduction of platelet aggregation, vasodilation,  
12:04:07 10 anti-proliferation, plaque-stabilization, and  
12:04:10 11 reduction in lipid action."

12:04:12 12 And then it says, "Therefore the preventive  
12:04:14 13 effects of EPA on major cardiovascular events are of  
12:04:20 14 both clinical interest and therapeutic importance,"  
12:04:23 15 correct?

12:04:23 16 A Yes.

12:04:25 17 MS. HUTTNER: And actually, Steven, if you could  
12:04:26 18 go back to the original slide. Thank you.

12:04:26 19 BY MS. HUTTNER:

12:04:32 20 Q I've highlighted vasodilation because I want to start  
12:04:36 21 with that.

12:04:36 22 A Yes.

12:04:36 23 Q Do you have an understanding based on your review of the  
12:04:39 24 Yokoyama article and the references in that article what  
12:04:42 25 Yokoyama is referring to here?

12:04:43 1 A Yes. This is related to the nitric oxide synthesis and  
12:04:49 2 endothelial cells that regulates the vascular tone. So  
12:04:54 3 vasodilation is the same as relaxation. This would be  
12:04:57 4 considered a good thing.

12:04:59 5 Q Okay. And does this disclosure in Yokoyama, that the  
12:05:02 6 biological functions of EPA include vasodilation, does that  
12:05:07 7 relate to any of the physiological effects that Dr. Mason  
12:05:12 8 identifies in paragraph 5 in his report?

12:05:14 9 A Yes, improved endothelial function.

12:05:18 10 Q If we can go to -- but my next question to you is going  
12:05:20 11 to be how do you know that. Let's go to DDX 9.39.

12:05:28 12 And just to orient ourselves on this slide, we have  
12:05:32 13 the same excerpt from Yokoyama that we were just looking at,  
12:05:37 14 and you have reproduced the references that Yokoyama is  
12:05:42 15 relying on in relation to vasodilation, correct?

12:05:46 16 A Yes.

12:05:46 17 Q And the bubble on the right is the discussion in the  
12:05:50 18 underlying reference that that's -- that is informing your  
12:05:55 19 understanding of what Yokoyama means by vasodilation, correct?

12:05:59 20 A That is correct.

12:05:59 21 Q And in the highlighted Okuda article, which is one the  
12:06:04 22 references Yokoyama relies on, and I'm not going to go through  
12:06:06 23 all the words, but there's a discussion of the nitric oxide  
12:06:13 24 and how EPA affects the endothelial production of nitric  
12:06:19 25 oxide, correct?

12:06:19 1 A Yes.

12:06:19 2 Q And is that essentially the same thing that Dr. Mason  
12:06:22 3 discusses in his report in relation to stabilization of cell  
12:06:30 4 membrane?

12:06:31 5 A Yes, it is.

12:06:32 6 MS. HUTTNER: If we can go back to DDX 9.119,  
12:06:32 7 please.

12:06:32 8 BY MS. HUTTNER:

12:06:42 9 Q Okay. Again, we're back in Yokoyama. This is the same  
12:06:44 10 disclosure we were discussing, but I want to talk in the first  
12:06:47 11 instance now about Yokoyama's disclosure that the biological  
12:06:51 12 functions of EPA include plaque stabilization.

12:06:55 13 What do you understand Yokoyama to mean by plaque  
12:06:58 14 stabilization?

12:06:59 15 A Well, as I mentioned before, unstable plaques are prone  
12:07:03 16 to rupture and cause heart attacks. So plaque stabilization  
12:07:07 17 would be preventing that to happen to increase the  
12:07:14 18 characteristics of a plaque that make it less likely to become  
12:07:18 19 unstable and then cause a heart attack.

12:07:20 20 Q And does the plaque stabilization described in Yokoyama,  
12:07:24 21 does that differ in any way from the plaque stabilization  
12:07:28 22 regression of plaque feature that Dr. Mason mentions in  
12:07:32 23 paragraph 5 of his report?

12:07:33 24 A It's equivalent to that.

12:07:35 25 Q How about the next term in Yokoyama, reduction in lipid

12:07:44 1 action. What do you understand that to mean?

12:07:47 2 A That is referring to the ability of certain lipid  
12:07:53 3 metabolites to cause a number of adverse effects on cells,  
12:07:59 4 including damaging their membranes, causing the production of  
12:08:04 5 inflammatory molecules and inflammatory mediators promoting  
12:08:10 6 the recruitment of macrophages into the plaque.

12:08:15 7 So there's a whole variety of downstream adverse  
12:08:18 8 consequences from the actions of certain lipids that can  
12:08:23 9 accumulate in the plaque.

12:08:24 10 Q And did you arrive at that understanding by looking at  
12:08:27 11 the references cited in Yokoyama in relation to reduction of  
12:08:32 12 lipid action?

12:08:33 13 A Yes, I did.

12:08:34 14 MS. HUTTNER: If we can go to DDX 9.38.

12:08:34 15 BY MS. HUTTNER:

12:08:41 16 Q Again, this is the same format as before, we have the  
12:08:44 17 excerpt from the Yokoyama article at the top and a  
12:08:48 18 reproduction of the references from the Yokoyama article in  
12:08:51 19 the bubble below that, and then on the right we have the an  
12:08:55 20 excerpt from, in this case, the ANDO reference, correct?

12:09:00 21 A Yes.

12:09:00 22 Q And do you rely for your interpretation of reduction of  
12:09:05 23 lipid action on the highlighted language in the ANDO article?

12:09:14 24 A Yes, I do.

12:09:15 25 Q Okay. And can you briefly explain what -- why you

12:09:22 1 consider this significant.

12:09:24 2 A Yes, because these authors are investigating the effect  
12:09:30 3 of EPA that is incorporated into the cellular membranes.

12:09:38 4 What they talk about here in that first highlighted  
12:09:40 5 area is the incorporation of the cellular phospholipids which  
12:09:47 6 means that EPA gets incorporated into building blocks of cell  
12:09:52 7 membranes.

12:09:52 8 That this -- the result of this incorporation into  
12:09:55 9 the cellular phospholipids decrease the conversion of LDL to a  
12:10:04 10 form that is often referred to as oxidized LDL, and this is a  
12:10:10 11 result of what's mentioned here as lipid peroxidation or a  
12:10:16 12 peroxidation process.

12:10:17 13 So downstream of lipid peroxidation is many of those  
12:10:25 14 negative consequences that I referred to before. They mention  
12:10:28 15 a few in this paragraph which we don't need to review in  
12:10:32 16 detail.

12:10:32 17 But basically what the bottom line here is that you  
12:10:36 18 prevent incorporating EPA into cellular membranes, you prevent  
12:10:43 19 the conversion of LDL to a form that has oxidized lipids that  
12:10:50 20 have a number of adverse effects on the cell and on the plaque  
12:10:56 21 as well.

12:10:57 22 Q And does disclosure of reduction lipid action in  
12:11:02 23 Yokoyama, does that relate or disclose any of the benefits  
12:11:05 24 that Dr. Mason cites in paragraph 5 of his report?

12:11:10 25 A Yes. In his report he goes over extensively the

1 importance of oxidized LDL as a negative factor so this speaks  
2 directly to some of that material.

3 Q And which of the four benefits -- let's just go back  
4 to -- go to DDX 9.104. Again, this is paragraph 5 from  
5 Dr. Mason's report.

6 Which of the, which of the functions identified in  
7 Dr. Mason's report does reduction of lipid action relate to?

8 A It would be particularly the first two, because, as I  
9 mention, this is incorporated into the membrane and is  
10 protective of the membrane so it would be stabilizing the  
11 membrane, and by not having those downstream actions of lipid  
12 peroxidation, you also would improve endothelial function.

13 Q All right. Now I want to direct you to another excerpt  
14 from the Yokoyama article.

15 MS. HUTTNER: Can we have DDX 9.89, please.

16 BY MS. HUTTNER:

17 Q Okay. This particular excerpt in DDX 9.89 is from page 7  
18 of DX 1563 which is the Yokoyama article -- I'm sorry, DX 1553  
19 which is the Yokoyama article, correct?

20 A Yes.

21 Q And in this excerpt, Yokoyama discloses that,

22 "Dietary fish oil reduces the production of  
23 chemoattractants, including leukotriene B4,  
24 platelet-derived growth factor, and monocyte  
25 chemoattractant protein 1. These mechanisms reduce

12:12:56 1 the passage of monocytes and macrophages into the  
12:12:59 2 plaque. Thus, EPA and DHA reduce the numbers of  
12:13:03 3 macrophages in the atherosclerotic plaque."

12:13:06 4 What is Yokoyama telling us here about the  
12:13:08 5 effects of EPA?

12:13:10 6 A That there is a reduced production of particularly  
12:13:17 7 important molecules that would promote the growth of the  
12:13:23 8 plaque as well as its level of inflammation.

12:13:26 9 For example, leukotriene B4 is a highly inflammatory  
12:13:37 10 molecule, and monocyte chemoattractant protein 1, which is  
12:13:43 11 usually abbreviated MCP-1, is a major mechanism by which the  
12:13:50 12 monocytes are called from the circulation because monocytes  
12:13:53 13 are white blood cells in all of us that in our circulation.

12:13:58 14 When there's a need for a macrophage to be in an  
12:14:05 15 inflammatory site like a plaque, there's a call to bring in  
12:14:11 16 monocytes from the circulation into the tissue, and these  
12:14:14 17 monocytes become the macrophages.

12:14:17 18 So if you decreased MCP-1 production, then you would  
12:14:23 19 have fewer monocytes entering the plaque and therefore fewer  
12:14:28 20 macrophages, and if you had less leukotriene B4 that was  
12:14:33 21 stimulating these macrophages, their inflammatory state would  
12:14:38 22 be less.

12:14:39 23 So the net result that would be expected from EPA  
12:14:42 24 through it's regulation of the production of these molecules  
12:14:45 25 would be fewer microphages in the plaque and they'd be less

12:14:51 1 activated.

12:14:51 2 Q So which, if any, of the functions identified by  
12:14:56 3 Dr. Mason does this excerpt from Yokoyama disclose?

12:15:00 4 A Well, it would be the two stabilization of plaque and  
12:15:05 5 regression because there would be fewer cells and they would  
12:15:09 6 be less angry or less activated, as well as the last bin that  
12:15:14 7 he has the anti-inflammatory effects. These would clearly be  
12:15:19 8 anti-inflammatory effects as well.

12:15:21 9 Q By the way, are any of the chemicals or substances  
12:15:25 10 identified in this passage, are any of them markers of  
12:15:28 11 inflammation?

12:15:30 12 A Well, markers, yes, high levels of leukotriene B4 are --  
12:15:36 13 actually high levels of monocyte chemoattractant protein 1  
12:15:41 14 have been taken as indicators of levels of inflammation.

12:15:49 15 Q So another article that you said you are relying on in  
12:15:55 16 the chart that we looked at earlier was an article by Omura  
12:16:00 17 correct?

12:16:00 18 A Yes.

12:16:00 19 Q And that was a 2001 article, right?

12:16:02 20 A Yes.

12:16:03 21 Q And what does Omura 2001 say about the physiological  
12:16:09 22 functions of EPA?

12:16:10 23 MS. HUTTNER: And, actually, can I have DDX  
12:16:14 24 9.46.

12:16:14 25

12:16:14 1 BY MS. HUTTNER:

12:16:14 2 Q And the Omura article is DX 2145 is that one of the  
12:16:22 3 articles you relied on in this case for your opinion?

12:16:24 4 A Yes.

12:16:24 5 Q And you reviewed that chart in detail?

12:16:26 6 A I did.

12:16:27 7 MS. HUTTNER: Your Honor, we would move DX 2145  
12:16:31 8 into evidence.

12:16:31 9 MR. SIPES: No objection, Your Honor.

12:16:32 10 THE COURT: 2145 is admitted.

12:16:32 11 (Defendant's Exhibit 2145 received in  
12:16:32 12 evidence.)

12:16:32 12 BY MS. HUTTNER:

12:16:36 13 Q Okay. So the right in DDX 9.46 you have an excerpt from  
12:16:41 14 page 1 of the Omura article, correct?

12:16:46 15 A Yes.

12:16:46 16 Q And does this excerpt discuss the physiological  
12:16:48 17 properties of EPA?

12:16:48 18 A Yes.

12:16:49 19 Q And can you tell us what's disclosed here.

12:16:52 20 A Well, it's related to the endothelial function, the  
12:16:57 21 ability of the endothelium, healthy endothelial cells to make  
12:17:02 22 nitric oxide which would be promoting vasodilation.

12:17:07 23 What's interesting to me about this article is that  
12:17:10 24 studies are done directly on arteries, porcine pig coronary  
12:17:15 25 arteries which -- even though this article is from 2001,

12:17:20 1 actually, pigs are still used as a very important model of  
12:17:26 2 human coronary artery disease.

12:17:29 3 And so he has reported beneficial effects of EPA in  
12:17:35 4 an important model of coronary artery disease, the pig, as  
12:17:40 5 well as doing more mechanistic studies in isolated endothelial  
12:17:48 6 cells in which he reports here that there was increased  
12:17:51 7 potentiation, just means there was increased release of nitric  
12:17:57 8 oxide which was originally discovered as endothelium derived  
12:18:02 9 relaxing factor.

12:18:04 10 So the overall conclusion at the bottom is a bit of  
12:18:07 11 a double negative way, it's improving endothelial function by  
12:18:14 12 decreasing endothelial dysfunction. So it's just a linguistic  
12:18:14 13 twist.

12:18:19 14 What these authors are concluding is that  
12:18:23 15 polyunsaturated fatty acids, especially EPA, overcomes  
12:18:28 16 endothelial dysfunction which means it's improving endothelial  
12:18:34 17 dysfunction -- it's improving endothelial function, which  
12:18:37 18 would be expected to suppress the atherogenic, that just means  
12:18:42 19 the development, the growth of the plaque processes.

12:18:45 20 Q And is there any overlap between this disclosure that you  
12:18:49 21 just described in Omura and the -- any of the physiological  
12:18:54 22 functions that Dr. Mason discusses in paragraph 5 of his  
12:18:57 23 report?

12:18:57 24 A Yes, improved endothelial function.

12:19:03 25 MS. HUTTNER: Now, Your Honor, I believe we're

1 going to have an objection in this next part. Do you want  
2 me -- do you want -- the objection -- let me just raise it.

3 There was a criticism of Dr. Fisher's reliance  
4 on the Omura article and Dr. Mason's reply report which  
5 obviously he didn't have an opportunity to respond to.

6 You know, the objection is that Dr. Fisher's  
7 report doesn't discuss this reference because obviously he was  
8 not aware of it until it surfaced in Dr. Mason's reply report.

9 We had intended to address that now. I think it  
10 is fair game, certainly, I guess we could wait until our  
11 rebuttal case, but it seems while we have Dr. Fisher on the  
12 stand that it makes sense to respond to that.

13 I believe their position is that we don't get to  
14 respond to that because he didn't foresee that Dr. Mason would  
15 rely on it in his reply report or, alternatively, that I  
16 should have elicited direct testimony from Dr. Fisher about  
17 the article at his deposition.

18 Neither position is one that I agree with, but  
19 Your Honor will rule.

20 THE COURT: So by the time of Dr. Fisher's  
21 deposition, he would have seen Dr. Mason's reply report? Is  
22 that basis for objecting as to why this information was not  
23 elicited at his deposition?

24 MS. HUTTNER: I believe that's his position,  
25 that I should have elicited from his -- at his deposition of

1 Dr. Fisher that I should have elicited testimony about aspects  
2 of Dr. Mason's reply report that he did not inquire about at  
3 the deposition.

4 MR. SIPES: Your Honor, if I could actually  
5 state my own objection?

6 MS. HUTTNER: I may have done a better job.

7 MR. SIPES: Well, I will incorporate her  
8 objection into mine, I suppose.

9 But, yeah, so they would like Dr. Fisher to  
10 testify about a technical article that is not anywhere cited  
11 in his report.

12 Their complaint now apparently is that it was  
13 cited in a reply report and therefore it should be fair game  
14 for them.

15 My view is if they had recognized in the reply  
16 reports -- there was quite a bit space between the reply  
17 reports and the depositions. If they had identified that they  
18 wanted to supplement Dr. Fisher's report with a response on  
19 this, they could have done so in advance of the deposition and  
20 I would have had an opportunity to question Dr. Fisher.

21 Indeed, there's been a lot of time in the case  
22 where we need to supplement Dr. Fisher's report and we'll give  
23 you an opportunity to question him on it. We could have done  
24 so.

25 Here we are in court, now they want to elicit

1 direct testimony from their technical expert, I've have had no  
2 opportunity to question the expert on this article.

3 MS. HUTTNER: Your Honor, I mean --

4 THE COURT: Ms. Huttner, that argument resonates  
5 with me in terms of fairness to both sides. That's the reason  
6 why you have extensive discovery and exchanges of reports.

7 And I understand that Dr. Fisher would have no  
8 reason to address it in his initial report, but at least by  
9 the time of his deposition, he could have testified to the  
10 article in the -- in Dr. Mason's reply or could have  
11 supplemented.

12 So how would you -- what's the counterpoint?

13 MS. HUTTNER: Well, Your Honor, I've been doing  
14 this -- I mean, the typical practice in at least in my  
15 experience in these kinds of cases, especially in this case, I  
16 mean, you may recall, we had 13 depositions, 13 expert  
17 depositions that took place within a month of reply reports  
18 coming in.

19 And, you know, frankly, in my experience  
20 normally the reply reports, because obviously they have the  
21 last word on a topic, are simply to the extent there's a  
22 question there, the examiner, the proponent of the reply  
23 report, in other words, usually asks about issues that  
24 they're -- that arise in the reply report.

25 I've not been involved in a situation in which I

1 was effectively put in a position of either having to elicit  
2 direct testimony about things not in the existing report at  
3 the deposition or I would have had to seek leave from the  
4 Court to file a supplemental opinion of Dr. Fisher.

5 I mean, there are many things in the reply  
6 report, not only of Dr. Mason but of Dr. Ismail that, you  
7 know, my -- that are criticisms of this or that in the main  
8 reports. You know, that -- this is a very short segment. I  
9 mean, essentially, Dr. --

10 THE COURT: Hang on. So clearly you felt  
11 that -- and Dr. Fisher felt that the information, this part of  
12 the information in the reply report is sufficient enough that  
13 he's going to testify.

14 So this is not an issue of referencing  
15 everything in the reply, and my concern -- like I said, the  
16 argument that now Mr. Sipes is not going to be prepared to  
17 address this part of the testimony because it hasn't -- he  
18 wasn't on notice that this will be addressed. How --

19 MS. HUTTNER: Well, Your Honor --

20 THE COURT: How do I alleviate that issue of  
21 surprise?

22 MS. HUTTNER: Okay. So two points, Your Honor.  
23 First of all -- and I could show this to you if you like.

24 But in Dr. Mason's report, there's a -- there's  
25 a number of statements about the Omura article, and then

12:24:09 1 there's a footnote with some more statements in it, and at the  
12:24:12 2 end of that footnote they cite to a particular article.

12:24:15 3 So they don't cite to any specific portion of  
12:24:17 4 the article, there's no PIN cite, you know, there's no  
12:24:20 5 really -- it's not even a hundred percent clear to me what  
12:24:23 6 he's citing that article for.

12:24:25 7 So, quite frankly, I would not have sought to  
12:24:29 8 put in a surreply report on that because there was just no way  
12:24:32 9 of telling what it was that Mason was relying on --

12:24:35 10 THE COURT: And how do you know now what he's  
12:24:37 11 replying on?

12:24:38 12 MS. HUTTNER: I don't know what he's relying on.  
12:24:41 13 Essentially what Dr. Fisher would testify to is that there's  
12:24:43 14 nothing in the article that supports the criticism, that's all  
12:24:45 15 he's going to say.

12:24:46 16 And the other thing he would say is that -- the  
12:24:48 17 specific criticism by Dr. Mason was that Omura used the wrong  
12:24:53 18 method to detect nitric oxide in the experiments, Omura's  
12:24:58 19 experiments that are described in that article.

12:25:00 20 So essentially all he's going to say is to identify  
12:25:04 21 what was that method, it's a method called the Dan method.

12:25:06 22 And then the only thing he's going to say about  
12:25:09 23 the reference is that that -- that assay, the Dan method, is  
12:25:14 24 disclosed in the reference that Dr. Mason relied on as an  
12:25:17 25 acceptable method for measuring nitric oxide in biological

12:25:22 1 samples. That's it. There's no technical discussion.

12:25:24 2 He is simply going say that the Mason article is  
12:25:27 3 a survey article, it discloses acceptable -- various  
12:25:27 4 acceptable methods of measuring nitric oxide and that the Dan  
12:25:36 5 assay that Omura used is one of those methods.

12:25:37 6 That's the entirety -- that's my offer of proof  
12:25:40 7 on this testimony.

12:25:40 8 And, you know, frankly, if Mr. Sipes wants to  
12:25:42 9 defer until the rebuttal case, and if he wants to take a  
12:25:48 10 short, very short deposition from Dr. Fisher to find out what  
12:25:51 11 he's going to say about it, if that's his concern, I'll be  
12:25:55 12 happy to do that.

12:25:56 13 But, as I say, all he's going say is this is a  
12:25:56 14 survey article, discloses a variety of acceptable methods, and  
12:26:03 15 one of the methods that it discloses is the method that Omura  
12:26:04 16 used.

12:26:05 17 MR. SIPES: Your Honor, a couple of quick  
12:26:06 18 points. I'm in trial now, I'm really not looking to take a  
12:26:10 19 deposition at the same time.

12:26:11 20 THE COURT: I can understand that, although you  
12:26:12 21 do have week break next week.

12:26:14 22 MS. HUTTNER: I'm not anxious either, Your  
12:26:16 23 Honor, don't get me wrong.

12:26:17 24 MR. SIPES: And I would say, because I feel this  
12:26:19 25 very strongly, it is not typical practice, it is certainly not

1 my typical practice to put on direct testimony from an expert  
2 of matters that are outside the opening report.

3 So I disagree with Ms. Huttner that this is  
4 somehow typical practice.

5 You know, it does seem like they are  
6 hypothesizing an issue where somehow they didn't have to alert  
7 us to this idea that they wanted to supplement earlier. I  
8 don't think Ms. Huttner has made that case.

9 If what she's saying here is that we will be  
10 given the same latitude to respond to points in their experts'  
11 reply reports with our experts when we put them on, I suppose  
12 that would be a level playing field and so we would be willing  
13 to go forward on that basis.

14 It does seem like they have, however, in this  
15 particular examination really gone into matters that are  
16 outside the report, but if this is what Ms. Huttner is saying  
17 should be the practice now --

18 THE COURT: Well, and it seems --

19 MS. HUTTNER: I don't think --

20 THE COURT: Hang on. Given the vasta (phon)  
21 case, it seems to me that perhaps it's best to leave this for  
22 defendant's rebuttal case.

23 MS. HUTTNER: That's fine.

24 THE COURT: Because you're also trying to guess  
25 as to what Dr. Mason will testify.

12:27:27 1 MS. HUTTNER: That's exactly what I was going it  
12:27:29 2 say. I mean, it's little bit weird here because we don't have  
12:27:32 3 the witness to which he's responding, and I have to anticipate  
12:27:34 4 what he's going say based on what's have in the report.

12:27:38 5 So I'm perfectly fine in waiting to see what  
12:27:39 6 Dr. Mason has to say about the Omura article, if anything, and  
12:27:43 7 whether he relies on this article, and, if he does, then I  
12:27:46 8 think we're within our rights to rebut that testimony. But I  
12:27:50 9 will happily defer to that point.

12:27:52 10 MR. SIPES: And, Your Honor, what is happening  
12:27:53 11 is there's an order for production the defendants have urged  
12:27:56 12 which is fine with us.

12:27:57 13 The reason this is happening is because they  
12:27:59 14 wanted to go first on invalidity so we did not address  
12:28:02 15 invalidity in our opening case, we'll do it in our third round  
12:28:06 16 so this is -- it's just the nature of the order --

12:28:08 17 THE COURT: No, I understand. I already agree  
12:28:09 18 with that approach.

12:28:10 19 And so I think what makes sense -- and I don't  
12:28:13 20 know what the parties' practice are, I'm just reacting to this  
12:28:17 21 based on my sense of fairness in terms of trial and the fact  
12:28:20 22 that one party shouldn't be able to surprise or ambush the  
12:28:24 23 other.

12:28:24 24 This is why we have extensive discovery, and I  
12:28:27 25 feel for you that there are a lot of depositions and expert

witnesses disclosed, but it doesn't mean that a party can have an expert address an issue that was not addressed in the report or in a subsequent deposition.

With that in mind, I think that -- I'm willing to defer this issue should it come up in the rebuttal. So let's move on to another --

MS. HUTTNER: That's fair, Your Honor.

Your Honor, it's 12:30 and I don't know whether -- I'm going to move on to a different reference, I don't know whether you want to break now or break later, up to you.

THE COURT: We probably should break now.

MS. HUTTNER: Okay. I was hoping you would come out that way, Your Honor.

THE COURT: All right. We'll take a break.

MS. HUTTNER: My colleagues are grateful too.

(The noon recess was taken.)

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12:29:11 1 RENO, NEVADA, FRIDAY, JANUARY 17, 2020, 12:47 P.M.

12:29:11 2 ---o0o---

01:10:28 3  
01:10:28 4 THE COURT: Please be seated.

01:10:30 5 MS. HUTTNER: May I resume, Your Honor?

01:10:32 6 THE COURT: Yes.

01:10:34 7 MS. HUTTNER: Can I have DDX 9.40, Mr. Gross.

01:10:34 8 DIRECT EXAMINATION RESUMED

01:10:34 9 BY MS. HUTTNER:

01:10:46 10 Q Okay. This is the chart that we looked at before that  
01:10:48 11 discusses the references that you rely on for your opinion  
01:10:52 12 that the properties identified by Dr. Mason in his --  
01:10:57 13 paragraph 5 of his opening report were disclosed in the prior  
01:11:01 14 art, and we've talked about Yokoyama and Omura.

01:11:06 15 And the next article I would like to ask you about  
01:11:09 16 is the Terano article, okay?

01:11:12 17 A Yes.

01:11:12 18 Q So let's start with --

01:11:15 19 MS. HUTTNER: Let's go to DDX 9.48.

01:11:15 20 BY MS. HUTTNER:

01:11:28 21 Q Now, before we talk about the snapshot on DDX 9.48, just  
01:11:33 22 to orient ourselves, the DX 2143, which is in the background  
01:11:40 23 here, that's copy of the Terano article; is that correct?

01:11:52 24 A Yes, I'm sorry.

01:11:52 25 Q Yes. That was a scintillating question, I can

01:11:52 1 understand.

01:11:55 2 So is the Terano article a reference that you read  
01:11:57 3 and relied on in your expert report?

01:12:00 4 A Yes, it is.

01:12:01 5 MS. HUTTNER: Your Honor, we would move the  
01:12:03 6 Terano article, DX 2143 into evidence.

01:12:07 7 MR. SIPES: No objection.

01:12:07 8 THE COURT: 2143 is admitted.

01:12:07 9 (Defendant's Exhibit 2143 received in  
01:12:07 evidence.)

01:12:09 10 BY MS. HUTTNER:

01:12:11 11 Q Okay. Now, the snapshot that's on DDX 9.48 that's on the  
01:12:15 12 screen is taken from page -- page 6 of DX 2143, correct?

01:12:25 13 A Yes.

01:12:25 14 Q And in this snapshot, is Terano discussing the properties  
01:12:30 15 of EPA?

01:12:32 16 A Yes.

01:12:33 17 Q And what does Terano say on that subject?

01:12:36 18 A Well, he's discussing in relationship to its  
01:12:40 19 anti-inflammatory actions, and says that these actions can  
01:12:48 20 probably be attributed to reduced synthesis of prostaglandins,  
01:12:54 21 particularly PGE2 and possibly LTB which is that leukotriene B  
01:13:00 22 molecule we saw before.

01:13:02 23 So prostaglandins are known to give rise to many  
01:13:05 24 inflammatory molecules or mediators, so by reducing the  
01:13:10 25 synthesis of these molecules, it would be expected to have an

01:13:17 1 anti-inflammatory effect.

01:13:20 2 Q And it goes on to state in this snapshot, Terano  
01:13:24 3 concludes,

01:13:25 4 "Therefore, increased EPA intake could offer  
01:13:28 5 a novel and nontoxic alternative to conventional  
01:13:32 6 anti-inflammatory therapy."

01:13:33 7 A Yes.

01:13:34 8 Q Does that further persuade you that what Terano is  
01:13:38 9 disclosing in this excerpt is the anti-inflammatory properties  
01:13:41 10 of EPA?

01:13:42 11 A Yes, it does.

01:13:43 12 Q Does the fact that CRP is not mentioned here, does that  
01:13:47 13 in any way matter in terms of the opinion you're expressing  
01:13:51 14 about what's disclosed in Terano?

01:13:53 15 A No. As I mentioned before, CRP is one of many markers of  
01:13:58 16 inflammation so that's not important.

01:14:01 17 Q And just for the record, which of the physiological  
01:14:05 18 effects that Dr. Mason identifies in paragraph 5 does the  
01:14:08 19 Terano disclosure overlap with?

01:14:11 20 A The anti-inflammatory one.

01:14:16 21 MS. HUTTNER: All right. Let's move on to the  
01:14:18 22 Surette article. May I have DDX 9.51, please, Mr. Gross.

01:14:18 23 BY MS. HUTTNER:

01:14:23 24 Q Okay. And, again, let's just get oriented here. In the  
01:14:28 25 background is DX 2144, correct?

01:14:33 1 A Yes.

01:14:33 2 Q And DX2144 is the Surette article that you relied on?

01:14:37 3 A It is.

01:14:38 4 Q And you reviewed that article and cite to it in your  
01:14:41 5 expert report?

01:14:42 6 A I did.

01:14:43 7 Q Okay. Now, you have some other -- you have a number of  
01:14:48 8 call-outs on the slide, and on the right, there is a diagram,  
01:14:53 9 a picture, I think used the term cartoon in describing these  
01:14:57 10 kinds of pictures, right?

01:14:58 11 A Yes.

01:14:59 12 Q So what's in that, what's that cartoon showing?

01:15:02 13 A It's showing in the context of a cell where the authors  
01:15:07 14 think these actions of EPA would be occurring, and it points  
01:15:16 15 out the -- looks like a -- I wouldn't call it a pizza, but  
01:15:23 16 that structure with the membrane protein blue thing embedded  
01:15:28 17 in it, that's a cartoon of the membrane, the type of membrane  
01:15:32 18 that surrounds all our cells.

01:15:34 19 It makes a point that the omega-3 fatty acids are  
01:15:39 20 incorporated into the cell membranes particularly in that  
01:15:45 21 phospholipid molecule that we talked about before.

01:15:47 22 So that when you have incorporation of the omega-3  
01:15:54 23 fatty acids in the membranes, they have a number of beneficial  
01:15:58 24 functions before we learned that they decreased the  
01:16:04 25 peroxidation of LDL. Here, he's showing, the authors are

showing other benefits of that incorporation.

We have the downstream signaling from these molecules so that with the effects to diminish the production of those prostaglandins and, again, leukotrienes. There would be effects as far down as in the nucleus to change the expression of inflammatory pathways in cells that are found in the plaque.

We talked about monocytes becoming macrophages. So without getting too Biology 101, just to point out that a lot is encapsulated in this review.

That the incorporation of omega-3 fatty acids occurs in membranes. They have a number of beneficial effects on membrane stabilization, as well as the decreased production of inflammatory molecules, as well as decreased activation of the types of cells that can cause problems in plaques.

Q All right. Now, in the middle, in the second -- well, in the first call-out, is Surette simply saying that omega-3 fatty acids are incorporated into cell membranes?

A In the --

Q Yeah, it says, "In particular dietary omega-3 fatty acids" --

A Yes.

Q -- "compete with the omega-6 family of dietary polyunsaturated fatty acids for incorporation into all cell membranes."

01:17:50 1 That's what you were just describing, right?

01:17:51 2 A Yes, that is correct.

01:17:52 3 Q In the second snapshot on the bottom in the middle of DDX  
01:17:58 4 9.51, it says, "Dietary omega-3 fatty acids" -- and that would  
01:18:02 5 include EPA, correct?

01:18:04 6 A Yes.

01:18:04 7 Q -- "directly affect arachidonic acid metabolism  
01:18:11 8 because they displace arachidonic acid from membranes  
01:18:16 9 and compete with arachidonic acid for the enzymes  
01:18:20 10 that catalyze the biosynthesis of thromboxanes,  
01:18:25 11 prostaglandins and leukotrienes."

01:18:27 12 Let's just stop there for a moment. What does that  
01:18:30 13 mean?

01:18:30 14 A Well, we've heard about particularly prostaglandins and  
01:18:34 15 leukotrienes, and they are derived from arachidonic acid, and  
01:18:41 16 if you don't allow arachidonic acid to be incorporated by  
01:18:50 17 competition, essentially, if you have enough EPA or DHA to be  
01:18:55 18 incorporated, you would exclude arachidonic acid from being  
01:19:00 19 incorporated, and this would decrease the pool of arachidonic  
01:19:04 20 acid that would be converted to the inflammatory molecules  
01:19:09 21 that are prostaglandins and leukotrienes.

01:19:12 22 Q And it goes on in that same excerpt to say,

01:19:16 23 "Thus the net effect of consuming foods  
01:19:19 24 enriched in omega-3 fatty acids is a diminished  
01:19:23 25 potential for cells like monocytes, neutrophils and

01:19:26 1 eosinophils to synthesize these powerful arachidonic  
01:19:30 2 acid-derived mediators of inflammation and a  
01:19:33 3 diminished potential for platelets to produce a  
01:19:37 4 prothrombotic agent thromboxane A."

01:19:40 5 What does that -- is the author talking about  
01:19:41 6 there?

01:19:41 7 A Well, he has that's a lot of things in there.

01:19:45 8 Just to try to keep it short, the inflammatory  
01:19:50 9 mediators that we just discussed would have effects on the  
01:19:56 10 level of inflammation.

01:19:58 11 The very last part actually is hooking this,  
01:20:04 12 connecting this to an anti-thrombotic effect of EPA.

01:20:09 13 We mentioned before we -- I mentioned before that  
01:20:13 14 the clot that forms after a plaque ruptures is what causes the  
01:20:19 15 heart attack.

01:20:20 16 What they're saying here is there might be less of a  
01:20:24 17 chance of a clot to form as a result of having increased  
01:20:31 18 omega-3 fatty acids in the membranes of the cells.

01:20:35 19 Q Okay. And which physiological functions of EPA  
01:20:39 20 identified in paragraph 5 of Dr. Mason's report does Surette  
01:20:44 21 disclose in your opinion?

01:20:45 22 A Primarily the anti-inflammatory, but also plaque  
01:20:53 23 stabilization because, as I mentioned before, an unstable  
01:20:57 24 plaque has a very high level of inflammation.

01:21:00 25 MS. HUTTNER: Your Honor, I don't recall if I

01:21:02 1 moved DX 2144 into evidence. That's the Surette article.

01:21:06 2 But, if not, if I haven't done it already, I would like to do  
01:21:09 3 it so now.

01:21:10 4 THE COURT: You haven't. Is there any  
01:21:11 5 objection?

01:21:11 6 MR. SIPES: No objection, Your Honor.

01:21:12 7 MS. HUTTNER: Thank you, Your Honor.

01:21:13 8 THE COURT: 2144 is admitted.

01:21:13 9 (Defendant's Exhibit 2144 received in  
01:21:13 evidence.)

01:21:13 10 BY MS. HUTTNER:

01:21:16 11 Q Okay. So the last article that I want to discuss with  
01:21:19 12 you is the Suzuki article. I'm sorry, before we leave the  
01:21:23 13 Surette article, Surette was published prior to March 2008; is  
01:21:27 14 that correct?

01:21:27 15 A That is correct.

01:21:28 16 Q All right. Let's move on to Suzuki, which is another  
01:21:32 17 reference that you cite in support of your opinions.

01:21:36 18 MS. HUTTNER: And let's go to DDX 9.52, please.

01:21:36 19 BY MS. HUTTNER:

01:21:40 20 Q Okay. And, again, we have the same arrangement. We have  
01:21:44 21 on the left a picture of DX 2144, which is the -- I'm sorry,  
01:21:53 22 DX 2146, which is the Suzuki article, and on the right, we  
01:21:57 23 have an excerpt from that article taken from pages 1 and 2 of  
01:22:02 24 the Suzuki article.

01:22:03 25 For the record, Dr. Fisher, is DX 2146 the Suzuki

01:22:09 1 article that you rely on in your expert report?

01:22:11 2 A Yes.

01:22:12 3 Q And you reviewed that article?

01:22:13 4 A I did.

01:22:15 5 MS. HUTTNER: Your Honor, we would move DX 2146  
01:22:18 6 into evidence.

01:22:19 7 MR. SIPES: No objection, Your Honor.

01:22:20 8 THE COURT: 2146 is admitted.

01:22:20 9 (Defendant's Exhibit 2146 received in  
01:22:20 evidence.)

01:22:20 10 BY MS. HUTTNER:

01:22:23 11 Q All right. Now does Suzuki disclose the physiological  
01:22:26 12 properties of EPA?

01:22:27 13 A It does.

01:22:28 14 Q And what does Suzuki disclose on that subject?

01:22:31 15 A Well, it's primarily discussing the augmentation of the  
01:22:40 16 endothelium dependant vasodilatation that actually was  
01:22:45 17 observed in patients. This was a clinical study. And the  
01:22:52 18 mechanism that is likely to be responsible for that is  
01:22:58 19 included in the phrase enhancement of nitric oxide production.

01:23:05 20 We also just discussed on the previous slide the  
01:23:13 21 relationship of thrombosis to heart attacks, and so there's  
01:23:16 22 another desirable effect there.

01:23:21 23 And the inhibition of cytokine synthesis, those are  
01:23:27 24 inflammatory substances, inhibition of superoxide generation,  
01:23:33 25 that relates to the lipid actions that we talked about before,

the damaging peroxidation, the species that can damage membranes proteins in cells.

And finally the suppression of the leukocyte endothelium interaction, I described already how the monocytes first stick to the endothelium and then get passage inside to the plaque to become macrophages. So all of these would be considered beneficial.

Q Okay. Now, the -- I mean, the author does in fact use the term beneficial effects of EPA, right?

A Yes.

Q And it says in the first paragraph it says,  
"Although the precise mechanisms of these beneficial effects of EPA remain to be clarified, several possible mechanisms have been reported," and then it goes on to list the various properties or functions that you've just testified about.

My question to you, Dr. Fisher, is, do you understand Suzuki in this paragraph to be describing beneficial effects of EPA that were described in the literature before Suzuki wrote his article?

A Yes.

Q So at the time that Suzuki published this article, Suzuki was saying these properties of EPA are already known?

A Yes, he's briefly reviewing the state of the field and setting up their own set of studies that they performed.

01:25:04 1 Q And referring to those studies, the article goes on to  
01:25:07 2 talk about Suzuki's own experimental work, correct?

01:25:11 3 A Yes.

01:25:11 4 Q And in that experimental work, Suzuki's goal was to show  
01:25:15 5 that EPA had yet another beneficial property in addition to  
01:25:20 6 what's listed here as already known; is that right?

01:25:22 7 A Yes. That is correct.

01:25:23 8 Q And that additional beneficial property that Suzuki was  
01:25:27 9 looking for has -- is called -- has something to do with a  
01:25:30 10 term apoptosis; is that right?

01:25:33 11 A Yes, that's cell death. And they are aiming to  
01:25:40 12 investigate the protection of endothelial cells, ECs, against  
01:25:47 13 the cell death.

01:25:49 14 And can you imagine implicit in improvement in  
01:25:54 15 endothelial function, you need healthy endothelial cells so if  
01:25:59 16 they die, this is not going to be very good for atherotic  
01:26:08 17 plaque.

01:26:09 18 Q Okay. And just to get to be clear, the first part where  
01:26:11 19 he talks about the beneficial effects of EPA, he's saying  
01:26:14 20 here's what we already know about EPA, right?

01:26:16 21 A Yes.

01:26:17 22 Q And then he's hoping to discover something new.

01:26:19 23 A Correct.

01:26:20 24 Q Now, is there any overlap between this disclosure that  
01:26:28 25 you've described in Suzuki of the beneficial effects of EPA

01:26:31 1 and the beneficial effects of Vascepa or EPA that Dr. Mason  
01:26:38 2 identifies in paragraph 5 of his report?

01:26:40 3 A Yes.

01:26:41 4 Q Okay. And can you tell me what -- what functions  
01:26:44 5 identified by Dr. Mason in paragraph 5 of his report were  
01:26:48 6 disclosed in Suzuki.

01:26:50 7 A Essentially, all of them. This is a list that is  
01:26:56 8 relevant to all of them. We have the improvement in  
01:27:00 9 endothelial function here mentioned in two contexts, the NO  
01:27:05 10 production, as well as the vaso -- endothelium-dependent  
01:27:10 11 vasodilation, the stabilization of the membrane.

01:27:14 12 This is embedded in the inhibition of superoxide  
01:27:18 13 generation since superoxide damages membranes, the  
01:27:22 14 inflammation, anti-inflammatory because of the inhibition of  
01:27:22 15 cytokine synthesis.

01:27:22 16 And the stabilization and regression of plaques is  
01:27:30 17 related to the suppression of the leukocyte endothelium  
01:27:39 18 interaction because that will drive the number of inflammatory  
01:27:40 19 cells that are in the plaque, and so by decreasing them you  
01:27:45 20 would be stabilizing the plaque and promoting it's regression.

01:27:49 21 MS. HUTTNER: Okay. And, Your Honor, I would  
01:27:51 22 move the -- the Suzuki article, which is DX 2146, into  
01:27:56 23 evidence if I haven't already.

01:27:58 24 MR. SIPES: No objection, Your Honor.

01:27:59 25 THE COURT: 2146 -- I thought I admitted it

1 already. But if I haven't --

2 MS. HUTTNER: You may have, Your Honor. I'm --

3 THE COURT: I know there have been many --

4 MS. HUTTNER: I'm not even going to pretend like  
5 I can keep track.

6 BY MS. HUTTNER:

7 Q Just to be -- just so summarize your position,  
8 Dr. Fisher, is it your opinion that all of the physiological  
9 functions of EPA that Dr. Mason discusses in paragraph 5 of  
10 his report are -- were disclosed in the prior art prior to  
11 2008?

12 A Yes, that is my opinion.

13 Q And that a person of ordinary skill in the art would have  
14 been aware of that?

15 A Yes.

16 Q And is it also your opinion that all of the physiological  
17 functions identified by Dr. Mason in paragraph 5 of his  
18 opening report are inherent properties of EPA, the active  
19 ingredient, and not the result of the methods described in the  
20 asserted claims in this case?

21 A Yes.

22 Q Okay. Now, before -- before we leave paragraph 5 of  
23 Dr. Mason's -- at least this aspect of paragraph 5 of  
24 Dr. Mason's opening report, I would like to ask you a  
25 question.

01:29:19 1 MS. HUTTNER: I want to pull up, if I can,  
01:29:22 2 DDX 9.100, Steve.

01:29:22 3 BY MS. HUTTNER:

01:29:27 4 Q Okay. This is a reproduction of paragraph 19 from  
01:29:31 5 Dr. Mason's reply report. And I -- he begins by saying he  
01:29:37 6 disagrees with you that these mechanisms from paragraph 5 of  
01:29:41 7 his report were known before March 2008.

01:29:44 8 And then he goes on to say,

01:29:45 9 "Further, I believe that any limited  
01:29:47 10 understanding of EPA's physiological effects in March  
01:29:51 11 2008 would not have been sufficient to lead a person  
01:29:55 12 of ordinary skill in the art to expect that high  
01:29:56 13 purity EPA would provide the dramatic cardiovascular  
01:30:00 14 benefit that was ultimately observed in REDUCE-IT."

01:30:03 15 And I just want to be very clear here, sir. Did  
01:30:06 16 you, in your report, did you ever express the opinion that if  
01:30:09 17 a person of ordinary skill in the art prior to 2008 had been  
01:30:12 18 aware of the physiological effects of EPA, that based on that  
01:30:16 19 information alone they would have been able to predict the  
01:30:20 20 results in REDUCE-IT?

01:30:20 21 A I did not.

01:30:21 22 Q And do you believe that that's true?

01:30:23 23 A No.

01:30:24 24 Q Okay. Now, let's move on. Dr. Mason --

01:30:27 25 MS. HUTTNER: Let's go back to DDX9.105.

01:30:27 1 BY MS. HUTTNER:

01:30:35 2 Q Okay. Just again to reorient ourselves, this is the  
01:30:38 3 summary paragraph from Dr. Mason's report, paragraph 5, and I  
01:30:43 4 want to talk now about Dr. Mason's last opinion which is that  
01:30:48 5 there is, quote.

01:30:48 6 "...there is a strong basis to conclude that  
01:30:51 7 the cardiovascular risk reduction with Vascepa  
01:30:54 8 observed in a clinical trial called REDUCE-IT applies  
01:30:57 9 to patients with triglyceride levels greater than or  
01:31:01 10 equal to 500."

01:31:03 11 And I just want to clarify one point at the very  
01:31:06 12 beginning. The -- the intended triglyceride levels according  
01:31:12 13 to the REDUCE-IT study protocol were what?

01:31:14 14 A Between 200 and 499.

01:31:21 15 Q Right. And I believe --

01:31:22 16 A With a -- with changes in that category but in the high  
01:31:28 17 triglyceride group.

01:31:29 18 Q Okay. So just to be clear, the lower -- you're referring  
01:31:32 19 to the fact that the original REDUCE-IT protocol I think  
01:31:35 20 specified a lower bound of baseline triglyceride levels of  
01:31:41 21 135, and then that was subsequently raised --

01:31:44 22 A Yes.

01:31:45 23 Q -- to 200, correct?

01:31:45 24 A Correct.

01:31:45 25 Q Okay. But the upper bound the patients was supposed to

01:31:49 1 meet was 499, right?

01:31:50 2 A Yes.

01:31:51 3 Q So just south of the very high triglyceride territory?

01:31:55 4 A Yes.

01:31:55 5 Q Okay. And was -- there's been some testimony, I don't  
01:31:59 6 recall whether it's been in this case or in the depositions,  
01:32:02 7 but, nonetheless, there was some testimony I think from  
01:32:06 8 Dr. Ismail that if you look at the REDUCE-IT study report,  
01:32:09 9 some of the ranges report at the high end triglyceride levels  
01:32:13 10 above 500 in some patients; is that right?

01:32:17 11 A Correct.

01:32:18 12 Q And is there any way to tell from the REDUCE-IT report  
01:32:24 13 how many patients above 500 were enrolled or participated in  
01:32:30 14 REDUCE-IT?

01:32:30 15 A No.

01:32:30 16 Q In any event, was -- in your opinion, was the REDUCE-IT  
01:32:33 17 study designed to test the effects of Vascepa in patients with  
01:32:37 18 very high triglycerides?

01:32:38 19 A No, they were excluded, in fact, from the inclusion  
01:32:42 20 criteria.

01:32:43 21 Q And would REDUCE-IT have the ability -- from a  
01:32:46 22 statistical point of view, would it be sufficiently powered to  
01:32:52 23 detect any benefits in a patient population with triglycerides  
01:32:54 24 of 500 or higher?

01:32:57 25 A No.

01:32:57 1 MR. SIPES: Objection, Your Honor. He's  
01:32:59 2 offered -- he's entitled to offer his opinion on what it  
01:33:03 3 shows, which he stated. He's not been qualified as a  
01:33:06 4 statistical expert, and he expresses no opinion about the  
01:33:06 5 statistical power of REDUCE-IT.

01:33:06 6 MS. HUTTNER: I'll rephrase the question.

01:33:06 7 MR. SIPES: I would like the opportunity to make  
01:33:18 8 my own objections this afternoon.

01:33:18 9 MS. HUTTNER: I was trying to help you. I was  
01:33:19 10 trying to fix it, but I'll withdraw the question and ask a  
01:33:22 11 different one.

01:33:22 12 BY MS. HUTTNER:

01:33:22 13 Q Are there -- well, withdrawn.

01:33:26 14 So just to be clear, in your opinion, would the  
01:33:28 15 REDUCE-IT study be able to give any data on how Vascepa would  
01:33:32 16 affect patients above 500 in terms of providing any cardiac  
01:33:37 17 benefits?

01:33:37 18 A No.

01:33:38 19 Q That said, Dr. Fisher, do you agree with Dr. Mason that  
01:33:45 20 it is likely that patients with very high triglycerides on  
01:33:50 21 stable statin therapy would experience a cardiovascular  
01:33:52 22 benefit from take being Vascepa?

01:33:54 23 A Yes, I think that's plausible.

01:33:57 24 Q And if that -- if you accept that proposition that --  
01:34:03 25 that a test in a population of people that's 99 percent people

1 below 500 can be projected on to people above 500, what, if  
2 anything does that mean to you in terms of whether it's  
3 reasonable to project the JELIS results which were based on a  
4 patient population with -- that included people with  
5 borderline or high triglycerides? What.

6 Does that say to you about whether the JELIS results  
7 can be projected on to patients with the kinds of triglyceride  
8 levels that were involved in REDUCE-IT?

9 MR. SIPES: Objection, Your Honor. There is no  
10 such projection anywhere in his opening report.

11 MS. HUTTNER: On the contrary, there is. It's  
12 in paragraph 119 of his report where he comments on Dr. Toth's  
13 position that the art relied on by Dr. Heinecke is irrelevant  
14 because it doesn't have anybody below 500.

15 And he effectively says there that Dr. Toth  
16 can't have it both ways, that if the prior art is irrelevant  
17 because it doesn't include people above 500, then it's equally  
18 irrelevant to relate REDUCE-IT to people above 500 because  
19 there were no such people or no people involved -- above 500  
20 involved in that study.

21 MR. SIPES: Your Honor, as long as she puts it  
22 in -- that condition, that it's the -- the counterfactual,  
23 that's fine, that was how he expressed his opinion, that it's  
24 not true, but if it were true, then --

25 THE COURT: I'm sorry, I'm not able to

01:35:36 1 understand you at all.

01:35:37 2 MR. SIPES: He did not project JELIS on to the  
01:35:37 3 very high (unintelligible) patient populations. The opinions  
01:35:44 4 that he expressed is that if it were possible to project  
01:35:47 5 REDUCE-IT on to the very high triglyceride, then JELIS would  
01:35:50 6 follow.

01:35:51 7 MS. HUTTNER: I belief that was the question I  
01:35:52 8 was trying to ask, but I'll take your phrasing.

01:35:52 9 BY MS. HUTTNER:

01:35:56 10 Q If, as Dr. Mason says, it's reasonable to project the  
01:36:00 11 results of REDUCE-IT on to the -- I'm sorry, on to the very  
01:36:06 12 high triglyceride population, would it be equally reasonable  
01:36:10 13 in your opinion to project the results of JELIS on to the  
01:36:14 14 population of people involved in REDUCE-IT?

01:36:16 15 A I do.

01:36:16 16 Q And can you explain your thinking in that regard.

01:36:20 17 A Well, by the logic that the results in patients below 500  
01:36:29 18 would likely be obtained in patients above 500, that the same  
01:36:39 19 logic would be relevant to JELIS.

01:36:45 20 Q Okay. And, in your opinion, I mean, I alluded in  
01:36:51 21 speaking to Mr. Sipes to the fact that Dr. Toth took the  
01:36:54 22 position in his expert report in this case that essentially  
01:36:57 23 the art that Dr. Heinecke described during his testimony of  
01:37:01 24 the prior art didn't count, in effect, because it didn't have  
01:37:05 25 enough people or didn't have people above 500.

01:37:08 1 Do you recall that testimony?

01:37:09 2 A I do.

01:37:10 3 Q And in Dr. Toth's report, he, in effect, said you can't  
01:37:15 4 project that data on to the patient population of 500 or  
01:37:22 5 higher. Do you recall that?

01:37:23 6 A Yes.

01:37:23 7 Q And, in your opinion, is Dr. Toth's position with respect  
01:37:27 8 to the prior art that Dr. Heinecke discussed consistent with  
01:37:31 9 Dr. Mason's opinion that the REDUCE-IT results would apply to  
01:37:35 10 patients with triglycerides above 5500?

01:37:38 11 A No, they're inconsistent.

01:37:40 12 Q Let's move on. And you'll be happy to know we're  
01:37:45 13 approaching the end, Dr. Fisher and, probably the Court at  
01:37:48 14 well.

01:37:49 15 But the next topic I want to talk with you is  
01:37:51 16 another subject that you address in your expert report in this  
01:37:55 17 case, and that's the subject of nexus. Do you recall that?

01:37:59 18 A Yes, I do.

01:38:00 19 Q And I think we heard some testimony from Dr. Heinecke  
01:38:04 20 during his direct examination on Wednesday on the subject of  
01:38:07 21 nexus, correct?

01:38:08 22 A Yes.

01:38:08 23 Q And Dr. Heinecke testified about his understanding of the  
01:38:16 24 legal principles that an expert is supposed apply or that one  
01:38:20 25 is supposed apply in answering or trying to answer the

01:38:23 1 question of whether an alleged objective evidence of  
01:38:27 2 nonobviousness has a nexus to the asserted claims, correct?

01:38:31 3 A Yes.

01:38:33 4 MS. HUTTNER: And if we can go to DDX 9.92.

01:38:33 5 BY MS. HUTTNER:

01:38:36 6 Q In order to save time, DDX 9.92 is a picture, if you  
01:38:43 7 will, of the demonstratives that were used during  
01:38:46 8 Dr. Heinecke's testimony where Dr. Heinecke indicated that  
01:38:51 9 these are the legal standards that he applied in his analysis  
01:38:55 10 of objective evidence of nonobviousness and nexus.

01:38:59 11 Did you apply these same principles in connection  
01:39:02 12 with your opinions in this case?

01:39:04 13 A I did.

01:39:05 14 Q And did you reach any conclusions applying these  
01:39:12 15 principles as to whether any of the objective evidence --  
01:39:16 16 so-called objective evidence of nonobviousness discussed by  
01:39:20 17 either Dr. Ismail or Dr. Mason has a nexus to the patent  
01:39:26 18 claims which Amarin is asserting in this case?

01:39:28 19 A I did.

01:39:29 20 Q And what was that opinion?

01:39:30 21 A That there was no nexus.

01:39:31 22 Q All right. Now, have you prepared slides summarizing  
01:39:35 23 with respect to each of the -- each item of objective evidence  
01:39:39 24 discussed in the Ismail and Mason reports? Have you prepared  
01:39:44 25 a slide that sets -- summarizes your reasoning as to why you

01:39:47 1 reached that conclusion?

01:39:48 2 A I did.

01:39:49 3 MS. HUTTNER: So let's go DDX 9.55.

01:39:49 4 BY MS. HUTTNER:

01:39:56 5 Q And just again to orient yourself, at the top the chart  
01:39:59 6 it says -- it's got the quotation from Dr. Ismail's opinion  
01:40:04 7 that this slide relates to, correct?

01:40:07 8 A Yes.

01:40:07 9 Q And in this instance, DDX 9.55 is addressing Dr. Ismail's  
01:40:13 10 claim that there was a long-felt but unmet need for a  
01:40:16 11 triglyceride-lowering medication in diabetics with very high  
01:40:21 12 triglycerides that wouldn't raise their LDL-C and would lower  
01:40:26 13 their apo B. Correct?

01:40:27 14 A Yes.

01:40:28 15 Q And beneath that you have some bullet points where you  
01:40:31 16 summarize your -- the basis for your opinions that you don't  
01:40:34 17 think there's a nexus between that piece of objective evidence  
01:40:37 18 and claims.

01:40:37 19 And if you would, please walk us through each of the  
01:40:40 20 bullet points on the slide.

01:40:41 21 A Okay. The first point is that the claims are not limited  
01:40:44 22 to a method of treating diabetic patients.

01:40:48 23 The second is reducing LDL cholesterol and/or apo B  
01:40:53 24 has no nexus to claims that lack one or both of these  
01:40:56 25 limitations.

01:40:58 1 And the third is not commensurate in scope because  
01:41:01 2 not all patients taking 4 grams per day of Vascepa will  
01:41:06 3 experience a reduction in LDL cholesterol and/or apo B as has  
01:41:11 4 been shown by the MARINE study.

01:41:13 5 Q Okay. So I just want to talk about the second and third  
01:41:18 6 bullet points, and I want to do so briefly because I believe  
01:41:23 7 this was covered in part or substantial part maybe even in  
01:41:26 8 Dr. Heinecke's testimony. So let's go to DDX 9.56 [sic].

01:41:36 9 Okay. So DDX 9.96 is a reproduction of claim 1 from  
01:41:42 10 the '929 patent, right?

01:41:44 11 A Yes.

01:41:44 12 Q And is it your understanding that claim 1 is one the  
01:41:46 13 claims that Amarin is asserting in this case?

01:41:50 14 A Yes.

01:41:50 15 Q And in this claim is this any limitation relating to LDLC  
01:41:55 16 or apo B?

01:41:57 17 A No.

01:41:57 18 Q It's just a straight claim for reducing triglycerides  
01:42:00 19 with 4 grams a day of Vascepa, correct?

01:42:03 20 A Yes.

01:42:03 21 Q And are there other asserted claims that like claim 1 of  
01:42:06 22 the '929 patent do not contain either an LDL-C and/or apo B  
01:42:14 23 limitation?

01:42:15 24 A Yes, there are.

01:42:15 25 Q And have you prepared a chart listing those claims and

01:42:18 1 indicating which elements they lack?

01:42:19 2 A I did.

01:42:20 3 MS. HUTTNER: Okay. So could we go now to  
01:42:24 4 DDX 9.57.

01:42:24 5 BY MS. HUTTNER:

01:42:26 6 Q Okay. Is this the chart you prepared?

01:42:27 7 A It is.

01:42:27 8 Q Okay. And this chart you have a list of the claims that  
01:42:30 9 lack LDL-C and/or apo B limitations?

01:42:33 10 A Yes.

01:42:33 11 Q And those claims are -- as indicated in this chart, are  
01:42:39 12 the '728 patent claims 1 and 16, claim 1 from the '677 patent,  
01:42:46 13 claim 1 from the '652 patent, claims 4 and 17 from the '560  
01:42:52 14 patent, and claims 1 and 5 of '929 patent, and you have  
01:42:58 15 checkmarks to indicate which elements that they lack, whether  
01:43:00 16 it's apo B or LDL-C or both, correct?

01:43:05 17 A Yes.

01:43:06 18 Q And does this chart list all of the asserted claims that  
01:43:08 19 lack either an apo B or LDL-C limitation or both?

01:43:14 20 A Yes.

01:43:15 21 Q Okay. Now, the third bullet on your summary slide  
01:43:18 22 related to the fact that not everybody who takes Vascepa is  
01:43:22 23 going to experience either no change in LDL-C or decrease in  
01:43:28 24 apo B, right?

01:43:30 25 A Yes.

01:43:30 1 Q So is that another way of saying that the so-called  
01:43:33 2 benefit is not commensurate with the scope of the claims?

01:43:36 3 A Yes, it is.

01:43:37 4 Q All right. Let me direct your attention --

01:43:39 5 MS. HUTTNER: Let's go to DDX 9.58.

01:43:39 6 BY MS. HUTTNER:

01:43:41 7 Q And Dr. Heinecke discussed the information on this -- in  
01:43:49 8 this document before, right?

01:43:51 9 A Yes.

01:43:51 10 Q All right. And just again to orient yourself, this is  
01:43:53 11 from the MARINE study report?

01:43:55 12 A Yes, it is.

01:43:56 13 Q And it is looking at the percent change in LDL-C, right?

01:44:05 14 A Yes, it is.

01:44:06 15 Q And it's looking at the percent change in LDL-C across  
01:44:10 16 the patient population enrolled in the MARINE study.

01:44:14 17 A Yes.

01:44:15 18 Q And what -- what is shown on this slide that's relevant  
01:44:19 19 to your opinion that there's no nexus between Dr. Ismail's  
01:44:23 20 first opinion and the asserted claims?

01:44:26 21 A In the right-hand column, which is highlighted in yellow,  
01:44:31 22 that's the Amarin code name for Vascepa.

01:44:33 23 So on patients in the MARINE study that took 4 grams  
01:44:38 24 daily of Vascepa, at the end of the study the maximum LDL  
01:44:45 25 cholesterol level was -- and if you go down to the bottom of

01:44:50 1 that column, was 156 percent of the start.

01:44:56 2 Q So what does that tell you about what happened to the  
01:45:00 3 LDL-C levels of the patients in that group?

01:45:04 4 A In that group they clearly went up.

01:45:07 5 Q And in the -- and just to be fair here, I mean, the  
01:45:12 6 overall -- we're not talking about the mean data from the  
01:45:15 7 study, correct?

01:45:16 8 A That is correct.

01:45:17 9 Q So this is just in a particular percentage of the  
01:45:20 10 patients enrolled in this study experienced an increase in  
01:45:24 11 LDL-C as opposed to no change or decrease, correct?

01:45:27 12 A That is correct.

01:45:27 13 Q All right. Let's now go to -- oh, okay.

01:45:35 14 MS. HUTTNER: And, Your Honor, I just -- just  
01:45:36 15 for the record, DDX 9.58 comes from DX 1694, it's from  
01:45:44 16 page 273 of DX 1694, which is in evidence, and I'm now moving  
01:45:51 17 to DDX 9.61, which is taken from the same document from  
01:45:56 18 page 242.

01:45:56 19 BY MS. HUTTNER:

01:45:58 20 Q And in this portion of the MARINE study report, I believe  
01:46:01 21 they're discussing apo -- apo --

01:46:01 22 A Apo B.

01:46:08 23 Q Apo B, thank you, changes that happened during the course  
01:46:10 24 of the MARINE study; is that correct?

01:46:11 25 A That is correct.

01:46:12 1 Q So these were patients who were taking Vascepa, they  
01:46:14 2 looked at their apo B levels at the beginning and then they  
01:46:18 3 looked at them after treatment and compared them; is that  
01:46:21 4 fair?

01:46:21 5 A Yes.

01:46:21 6 Q Okay. And what is shown on this page from the MARINE  
01:46:25 7 study report?

01:46:25 8 A Well, it's laid out in a similar way, and we just now  
01:46:30 9 look at the percent change. The maximum percent change in the  
01:46:35 10 group taking the 4 grams daily of Vascepa was now 41 percent  
01:46:39 11 increased.

01:46:40 12 Q Okay. So that group of people did not experience any  
01:46:44 13 reduction in apo B as a result of taking Vascepa; is that  
01:46:48 14 correct?

01:46:48 15 A That is correct.

01:46:49 16 Q Your next summary slide I believe is DDX 9.62.

01:46:58 17 Okay. And just orient ourselves, this slide  
01:47:01 18 summarizes your -- the basis for your opinion that  
01:47:07 19 Dr. Ismail's next opinion, which is that Vascepa unexpectedly  
01:47:11 20 lowers cardiovascular risk, why you don't believe there's any  
01:47:15 21 nexus between that piece of secondary evidence and the claims  
01:47:19 22 in this case; is that right?

01:47:20 23 A That is correct.

01:47:20 24 Q Okay. And can you -- using the slide, can you explain  
01:47:25 25 the basis for your opinion that there's no nexus between

01:47:29 1 Dr. Ismail's opinion about unexpected results from REDUCE-IT  
01:47:35 2 and the asserted claims.

01:47:36 3 A Yes. There are five statements here.

01:47:39 4 The first is the claims are not directed to reduce  
01:47:44 5 cardiovascular risk.

01:47:45 6 The second is patients in REDUCE-IT had  
01:47:51 7 triglycerides less than 500 milligrams per deciliter.

01:47:56 8 The third is cardioprotective effects results were  
01:48:02 9 not seen until at least a year, whereas the claims specify  
01:48:07 10 12 weeks.

01:48:08 11 The fourth, all patients in REDUCE-IT were on stable  
01:48:13 12 statin therapy, whereas claims do not require statins and some  
01:48:20 13 prohibit additional lipid altering drugs.

01:48:24 14 And the fifth is REDUCE-IT results were not due to  
01:48:27 15 lowering triglycerides or LDL cholesterol or apo B.

01:48:33 16 Q Okay. So we'll -- just focusing on that last bullet for  
01:48:37 17 a second, the claims here are directed to methods of lowering  
01:48:45 18 triglycerides, that's at the heart of all the claimed methods,  
01:48:49 19 correct?

01:48:49 20 A Yes.

01:48:49 21 Q And the last bullet point, is that a reference to the  
01:48:52 22 fact that in the REDUCE-IT study report and in the Bhatt  
01:48:57 23 article that we've talked about, there was evidence in effect  
01:49:01 24 that triglyceride lowering -- in other words, the method in  
01:49:05 25 the claims, had nothing to do with the cardiac benefits

01:49:08 1 observed?

01:49:08 2 A Yes, that is correct.

01:49:09 3 Q And with respect to your second to last bullet here about  
01:49:14 4 stable statin therapy, just to expand a little bit, and I  
01:49:18 5 think Dr. Heinecke went into this so I won't belabor the  
01:49:22 6 point, but in some of the claims, is it your understanding  
01:49:25 7 that there is a limitation which refers to the patients not  
01:49:30 8 being on other lipid altering drugs?

01:49:33 9 A Yes.

01:49:33 10 Q And do you interpret other lipid altering drugs to  
01:49:39 11 include statins?

01:49:40 12 A Yes.

01:49:40 13 Q So in the case of those claims that have language that  
01:49:43 14 says that the patient should not be on other lipid-altering  
01:49:47 15 drugs, would REDUCE-IT have any relevance to that?

01:49:50 16 A No.

01:49:51 17 Q Were all of the patients in REDUCE-IT on stable statin  
01:49:54 18 therapy?

01:49:55 19 A Yes.

01:49:55 20 Q And is there any information in the REDUCE-IT study that  
01:49:59 21 tells you what would happen if you take Vascepa without being  
01:50:02 22 on statin therapy in terms a cardiac benefit?

01:50:05 23 A No.

01:50:06 24 Q That was not tested in REDUCE-IT, was it?

01:50:08 25 A No, it was not part of the design.

01:50:12 1 MS. HUTTNER: And let's go now to DDX 9.64.

01:50:12 2 BY MS. HUTTNER:

01:50:24 3 Q And this is your summary slide that you prepared  
01:50:27 4 explaining why you do not believe there is any nexus between  
01:50:31 5 the asserted claims and Dr. Mason's opinions, correct?

01:50:35 6 A Yes.

01:50:36 7 Q And I think the only objective evidence that Dr. Mason  
01:50:41 8 points to is the -- are the physiological effects of EPA that  
01:50:45 9 he claims were unknown in 2008, right?

01:50:48 10 A Correct.

01:50:48 11 Q And, in your opinion, does that -- does that alleged lack  
01:50:53 12 of knowledge, does that have any nexus to the asserted claims?

01:50:57 13 A Could you repeat that?

01:50:58 14 Q Yes, I'm sorry about that.

01:50:59 15 So, in your opinion, the so-called unexpected  
01:51:04 16 physiological effects that Dr. Mason identifies in his report,  
01:51:08 17 is there any nexus between those effects and those effects  
01:51:13 18 according to him not being known in 2008, is there any nexus  
01:51:17 19 between that and the asserted claims in this case?

01:51:20 20 A No.

01:51:20 21 Q And, again, if you could describe your reasons for that  
01:51:26 22 opinion.

01:51:27 23 A Yes, there are three statements here.

01:51:29 24 The first,

01:51:31 25 "Physiological effects identified by

01:51:34 1 Dr. Mason are inherent effects of EPA and are not due  
01:51:39 2 to the claimed methods of administering 4 grams of  
01:51:43 3 Vascepa per day to reducing triglycerides."

01:51:48 4 The second is,

01:51:49 5 "Most, if not all, of these same effects were  
01:51:52 6 identified in connection with JELIS, which did not  
01:51:57 7 involve administering 4 grams of EPA per day to  
01:52:01 8 patients with triglycerides greater than or equal to  
01:52:07 9 500 milligrams per deciliter."

01:52:08 10 And the last is,

01:52:09 11 "Asserted claims are not directed to any  
01:52:12 12 physiological effects of EPA; they are directed to  
01:52:15 13 method of treating very high triglycerides."

01:52:19 14 Q All right. I'll own responsibility for the typos on this  
01:52:23 15 chart. But have you now summarized the basis for your opinion  
01:52:28 16 that -- let me just ask you the question.

01:52:30 17 In your opinion, is there a nexus between any of the  
01:52:34 18 so-called objective evidence of nonobviousness discussed by  
01:52:39 19 Dr. Ismail and any of the claims that are asserted in this  
01:52:41 20 case?

01:52:42 21 A No.

01:52:44 22 MS. HUTTNER: Okay. Your Honor, I believe I  
01:52:46 23 have nothing further. I just want to check to see if I've  
01:52:49 24 admitted everything.

01:52:59 25 Your Honor, I'll pass the witness at this point.

01:53:01 1 THE COURT: Thank you.

01:54:35 2 (Discussion held off the record.)

01:54:35 3 MR. SIPES: Your Honor, Christopher Sipes behalf  
01:54:37 4 of Amarin, if I may proceed.

01:54:38 5 THE COURT: Yes.

01:54:39 6 CROSS-EXAMINATION

01:54:39 7 BY MR. SIPES:

01:54:39 8 Q Good afternoon, Dr. Fisher. You may recall we met at  
01:54:43 9 your deposition. My name is Christopher Sipes, and I'm here  
01:54:46 10 on behalf of the plaintiffs, Amarin.

01:54:48 11 A Good afternoon.

01:54:49 12 Q Let me just start by clarifying a few things. I believe  
01:54:52 13 you testified this morning that after Vascepa was approved,  
01:54:57 14 you did not switch your patients from Lovaza to Vascepa; is  
01:55:01 15 that correct?

01:55:01 16 A If they were doing well on it, that is correct.

01:55:04 17 Q And Vascepa, of course, was approved in 2012, correct?

01:55:09 18 A Yes.

01:55:09 19 Q Now, you testified at deposition, did you not, that you  
01:55:14 20 stopped seeing patients in 2010?

01:55:17 21 A No, I stopped having an outpatient practice and then  
01:55:22 22 switched to inpatient consultations.

01:55:28 23 MR. SIPES: Mr. Brooks, if we could just play  
01:55:31 24 page 46, lines 6 to eight.

01:55:31 25 (Deposition video recording played.)

01:55:31 1 BY MR. SIPES:

01:55:49 2 Q Now, let me ask you about your opinion that you didn't  
01:55:52 3 switch patients to Vascepa from Lovaza after it was approved  
01:56:01 4 in 2012.

01:56:02 5 In your reply report --

01:56:04 6 MR. SIPES: Mr. Brooks, if we could pull up DX  
01:56:07 7 1574, paragraph 23, and if I could have the exhibit number  
01:56:20 8 page to help out everybody, I apologize.

01:56:24 9 MR. BROOKS: Ten.

01:56:26 10 MR. SIPES: Ten, it would be page 10, so it's DX  
01:56:30 11 1574, page 10. And if you could just blow up the last  
01:56:33 12 sentence in the paragraph, Mr. Brooks. Just blow it up so  
01:56:37 13 even somebody with my bad eyes can read it.

01:56:37 14 BY MR. SIPES:

01:56:46 15 Q So in your report, did you not, Dr. Fisher, write that  
01:56:47 16 had Vascepa been approved at the time I was seeing patients in  
01:56:51 17 my clinical practice, I would have considered prescribing  
01:56:54 18 Vascepa as well. Is that what you wrote then?

01:56:56 19 A Yes.

01:56:56 20 Q I take it you've changed your mind now, and your view is  
01:56:59 21 you wouldn't switch patients from Lovaza to Vascepa.

01:57:03 22 A No, I say I would have considered prescribing Vascepa as  
01:57:06 23 well. That has nothing to do with switching patients from one  
01:57:09 24 drug to another.

01:57:11 25 Q All right. Now, you've testified briefly about a

01:57:14 1 subgroup analysis on Yokoyama, correct?

01:57:18 2 A Yes.

01:57:22 3 Q Does the Yokoyama paper discuss whether it's specifically  
01:57:26 4 powered for a subgroup analysis?

01:57:29 5 A It does not.

01:57:30 6 Q You don't recall it, being the Yokoyama, discussing  
01:57:33 7 whether or not it was powered for subgroup analysis, correct?

01:57:33 8 A I do not recall that.

01:57:34 9 MR. SIPES: Okay. Why don't we take a look at  
01:57:36 10 Yokoyama. If we could turn to DX 1553. Mr. Brooks, if you'd  
01:57:47 11 turn to page 0007, and first just blow up the start of the  
01:57:56 12 first full paragraph on the right that begins, "Our trial has  
01:58:00 13 several limitations," on the right.

01:58:00 14 BY MR. SIPES:

01:58:03 15 Q You see in this column, the authors are discussing a  
01:58:07 16 certain number of limitations to the JELIS trial, correct?

01:58:10 17 A Yes.

01:58:11 18 MR. SIPES: And then, Mr. Brooks, if you would  
01:58:13 19 pull up two paragraphs down that begins "third." And again  
01:58:19 20 highlight the first sentence.

01:58:19 21 BY MR. SIPES:

01:58:25 22 Q The authors state, "Third, this trial was substantially  
01:58:29 23 underpowered for analysis of subgroups," did they not?

01:58:32 24 A That's what it says.

01:58:33 25 Q Okay. And "by this trial," they're referring to JELIS

01:58:37 1 trial, correct?

01:58:38 2 A Yes.

01:58:38 3 Q The REDUCE-IT trial was differently powered, correct?

01:58:41 4 A That is correct.

01:58:41 5 Q And one of the reasons the REDUCE-IT trial was much more  
01:58:45 6 powered than the JELIS trial is, unfortunately, cardiovascular  
01:58:48 7 events occur with much greater frequency in the United States.

01:58:52 8 A Compared to Japan, that is -- that is true.

01:58:55 9 Q Okay. And that gave the REDUCE-IT trial greater power,  
01:58:59 10 correct?

01:59:00 11 A Well, the types of patients that were selected for  
01:59:04 12 REDUCE-IT also were at higher risk by design --

01:59:08 13 Q Right. The REDUCE-IT --

01:59:08 14 A -- than in JELIS.

01:59:09 15 Q The REDUCE-IT patients were different than the JELIS  
01:59:12 16 patients, correct?

01:59:13 17 A In terms of their cardiovascular risk, I think that's a  
01:59:16 18 fair statement.

01:59:17 19 Q Among other things, their baseline triglyceride levels  
01:59:20 20 were higher than the ones in the JELIS trial, correct?

01:59:23 21 A Yes.

01:59:23 22 Q And we'll look at that, but just let's take a quick look  
01:59:33 23 at -- you spent a lot of time on Dr. Mason's opinions to see  
01:59:37 24 what his opinions were about.

01:59:38 25 MR. SIPES: Mr. Brooks, if you could pull up

01:59:40 1 DDX 9.104, and it's not highlighted there, but it would be  
01:59:50 2 helpful to sort of blow up the bottom sentence so that at  
01:59:56 3 least we can get a sense of what Mr. Mason was talking  
01:59:58 4 about -- or what Dr. Mason was talking about.

01:59:58 5 BY MR. SIPES:

02:00:00 6 Q He's talking about the fact that in his opinion there's a  
02:00:03 7 strong basis to conclude that the cardiovascular risk  
02:00:07 8 reduction with Vascepa observed in clinical trial called  
02:00:11 9 REDUCE-IT applies to patients with TG levels greater than  
02:00:15 10 500 milligrams per deciliter, correct?

02:00:17 11 A Yes.

02:00:17 12 Q Dr. Mason didn't disagree with you. You cannot predict  
02:00:23 13 the REDUCE-IT results from these biological mechanisms, what  
02:00:27 14 he was trying to say is looking at the REDUCE-IT results  
02:00:30 15 themselves, do the biological mechanisms confirm that  
02:00:32 16 REDUCE-IT would apply to very high triglyceride patients,  
02:00:36 17 correct?

02:00:36 18 A I don't agree with that.

02:00:37 19 Q Okay. In any event, one question in this case is does  
02:00:44 20 the REDUCE-IT results apply to patients with severe  
02:00:48 21 hypertriglyceridemia, correct?

02:00:51 22 A It's plausible.

02:00:52 23 Q Well, you've expressed opinion that in fact the REDUCE-IT  
02:00:54 24 results do not apply to patients with severe  
02:00:57 25 hypertriglyceridemia.

02:00:58 1 A I can't evaluate it based on the design of the study.

02:01:01 2 Q And, of course, you also had the clinical study report,  
02:01:05 3 correct?

02:01:05 4 A Yes.

02:01:05 5 Q Yeah. But you're still not willing to say that the  
02:01:09 6 REDUCE-IT results apply to patients with severe  
02:01:13 7 hypertriglyceridemia, correct?

02:01:14 8 A You just told me JELIS was underpowered. REDUCE-IT was  
02:01:20 9 underpowered by design to test an hypothesis in patients with  
02:01:25 10 triglycerides over 500.

02:01:27 11 Q So just to be clear, it is your opinion that the  
02:01:29 12 REDUCE-IT trial does not show cardiovascular benefit for  
02:01:34 13 patients with severe hypertriglyceridemia who are administered  
02:01:38 14 4 grams per day of Vascepa, correct?

02:01:41 15 A I don't see that in the published paper.

02:01:43 16 Q Okay. And you don't see that in the clinical study  
02:01:47 17 report either?

02:01:47 18 A I cannot say that I examined the clinical study report on  
02:01:54 19 that point.

02:01:55 20 Q FDA, of course, had the clinical study report, correct?

02:01:58 21 A They did.

02:01:59 22 Q Right. Now, Mr. Mason's opinions trying to confirm the  
02:02:04 23 applicability of REDUCE-IT to severe hypertriglyceridemia  
02:02:09 24 patients came before FDA acted on the REDUCE-IT indication,  
02:02:16 25 the SNDA, for approval of the cardiovascular risk reduction,

02:02:20 1 correct?

02:02:21 2 A Yes.

02:02:21 3 Q And the opinions you expressed in your report also came  
02:02:25 4 before FDA acted on the SNDA, correct?

02:02:29 5 A Definitely.

02:02:30 6 Q We now, of course, have FDA's answer, correct?

02:02:35 7 MS. HUTTNER: Your Honor, I object this. This  
02:02:36 8 is well outside of the scope.

02:02:37 9 He's wanting to introduce the FDA approval, and  
02:02:41 10 I believe, based on that fact that the FDA approval doesn't  
02:02:46 11 have an upper limit to the indication in terms of triglyceride  
02:02:50 12 level, to suggest that somehow the FDA has indirectly  
02:02:54 13 determined that REDUCE-IT study results apply to patients at  
02:02:58 14 500 or higher, and I do not believe there's foundation to do  
02:03:01 15 that, and I would object to that. It's certainly beyond the  
02:03:04 16 scope of Dr. Fisher's testimony.

02:03:06 17 MR. SIPES: Your Honor, first of all, Dr. Fisher  
02:03:08 18 opined on the new Vascepa labeling earlier today. They pulled  
02:03:12 19 up the new labeling and had him opine on elements of the new  
02:03:16 20 cardiovascular labeling. I should be entitled to do the same  
02:03:19 21 thing.

02:03:20 22 MS. HUTTNER: He did not opine about the label,  
02:03:23 23 he simply pointed to the statement that is on the label  
02:03:25 24 regarding the mechanism of action of Vascepa as far as cardiac  
02:03:30 25 risk.

02:03:30 1 But what he is going to do, as I said, I believe  
02:03:32 2 he's trying to tie the indication that the FDA approved to  
02:03:36 3 patients with triglycerides above 500.

02:03:39 4 And there's simply nothing in -- although they  
02:03:41 5 didn't provide all of their submissions to the FDA, there's  
02:03:45 6 simply nothing in any of the documents that they did produce  
02:03:47 7 to suggest that that was a topic of conversation with FDA at  
02:03:50 8 all in this --

02:03:51 9 THE COURT: But isn't that an argument that you  
02:03:53 10 can make? Because, in other words, I thought initially your  
02:03:57 11 objection was that Dr. Fisher -- that the question about the  
02:04:02 12 FDA's approved label, which was only released in December,  
02:04:06 13 exceeds the scope of Dr. Fisher's report.

02:04:10 14 MS. HUTTNER: The -- what I'm trying to  
02:04:12 15 articulate is, I guess, two things. Number one, we have had  
02:04:18 16 no -- as you know, we have had no production or  
02:04:22 17 identification -- we don't know what was discussed between  
02:04:24 18 Amarin and the FDA except insofar as it relates to just the  
02:04:29 19 terms of label, okay?

02:04:31 20 So we have no evidence or even opportunity to  
02:04:35 21 determine whether in any of the conversations they had with  
02:04:38 22 FDA there was any discussion about people in the very high --

02:04:44 23 MR. SIPES: Your Honor, this is just not true.

02:04:45 24 THE COURT: Mr. Sipes, please let Ms. Huttner  
02:04:48 25 finish.

02:04:49 1 MS. HUTTNER: So, you know, the FDA gave an  
02:04:51 2 approval for a specific indication where the lower limit of  
02:04:56 3 that indication was you had to have triglycerides, I think, of  
02:05:00 4 150 plus some other things to be included in the new cardiac  
02:05:04 5 indication, okay? Is this making -- so --

02:05:09 6 THE COURT: So it seems like the objection now  
02:05:11 7 is a little bit different.

02:05:13 8 I'm trying to ground this in the question that  
02:05:15 9 was asked because it seems like you're raising the issue I  
02:05:18 10 already -- now, I can't even talk and I'm speaking normal  
02:05:23 11 language, not all these terms that are somewhat challenging to  
02:05:27 12 the tongue.

02:05:31 13 But it seems like your objection now is merged  
02:05:34 14 to the issue I resolved with respect to the motion in limine  
02:05:37 15 in terms of what's been produced.

02:05:39 16 MS. HUTTNER: No, not really. Let me try to  
02:05:41 17 articulate a little bit more clearly what my concern is.  
02:05:44 18 Okay?

02:05:45 19 So, it is -- so the question that was asked is  
02:05:48 20 about to get in, I believe, to a suggestion that FDA said  
02:05:54 21 REDUCE-IT applies to patients above 500, okay?

02:05:57 22 He did not testify about anything about the --  
02:06:04 23 that subject during his direct examination.

02:06:07 24 The only reference he made to the Vascepa label  
02:06:10 25 was to the mechanism of action section where it simply said we

02:06:15 1 don't know.

02:06:15 2 So I don't think it's fair to get into this. I  
02:06:18 3 don't think it's part of what Dr. Fisher has testified about  
02:06:25 4 in this case, and I think it's an unfair question as well  
02:06:28 5 because we don't have the materials even that -- to the extent  
02:06:31 6 that he's allowed to get into this, that we could possibly  
02:06:35 7 respond with because of the lack of production of any  
02:06:38 8 correspondence other than that relating to the specific words  
02:06:42 9 in the label.

02:06:43 10 THE COURT: Mr. Sipes?

02:06:43 11 MR. SIPES: Couple points. One, focusing on  
02:06:46 12 what they had just reverse (unintelligible). They have all  
02:06:49 13 the labeling correspondence which is what we're talking about  
02:06:51 14 the labeling.

02:06:52 15 Two, they have extensive discussion of the  
02:06:55 16 substance of the REDUCE-IT results and how it relies,  
02:06:59 17 including thousands of pages from the ad com which they have  
02:07:02 18 been constantly rehearsing in this case.

02:07:04 19 THE COURT: All right. I'm not persuaded by the  
02:07:06 20 argument as to what the defendants do not have. So next issue  
02:07:09 21 then.

02:07:09 22 MR. SIPES: They have had him opine on what the  
02:07:12 23 current labeling says.

02:07:14 24 Now, we could take it question by question, but  
02:07:16 25 I should be able to ask him questions about the current

02:07:19 1 labeling, too.

02:07:19 2 He has opined on the meaning of certain sections  
02:07:22 3 the labeling. I should be able to ask him -- and including by  
02:07:26 4 doing the nexus what the indications are.

02:07:28 5 So I should be able to ask him questions. If  
02:07:30 6 they think the question goes beyond his expertise or his  
02:07:34 7 opinions, they can object. But the notion that I cannot pull  
02:07:38 8 up the labeling and ask him about it seems to me a very  
02:07:43 9 overbroad objection.

02:07:43 10 THE COURT: I agree, I think it's fair that  
02:07:45 11 given the fact that Dr. Fisher was asked about the new label  
02:07:49 12 which is Exhibit 1186, that at least Mr. Sipes should be able  
02:07:55 13 to ask questions about other portions the label.

02:07:58 14 And if the objection is that there -- the  
02:08:00 15 particular question exceeds the scope of his -- what's been  
02:08:05 16 disclosed as to his expertise, I'll consider the objection  
02:08:09 17 question by question.

02:08:11 18 MS. HUTTNER: Thank you, Your Honor.

02:08:14 19 MR. SIPES: All right. If we could pull up PX  
02:08:18 20 1186. Mr. Brooks, if you could turn -- that page, blow up the  
02:08:22 21 indication and the limitation of use underneath it.

02:08:22 22 BY MR. SIPES:

02:08:29 23 Q Now, you recognize that there are two indications in the  
02:08:33 24 Vascepa labeling, correct? One for a reduction of  
02:08:36 25 cardiovascular risk, and one for use as an adjunct to diet to

02:08:41 1 reduce triglyceride levels in adult patients with severe  
02:08:46 2 hypertriglyceridemia, correct?

02:08:47 3 A Yes, I do.

02:08:48 4 Q And to make the point that Ms. Huttner was pointing out,  
02:08:51 5 there was a minimum level of triglycerides that are required  
02:08:54 6 for the REDUCE-IT indication, correct?

02:08:56 7 A Correct.

02:08:57 8 Q And that's a 150 milligrams per deciliter.

02:09:01 9 A Yes.

02:09:01 10 Q And that 150 is the standard for when triglycerides go  
02:09:06 11 from normal to elevated, correct?

02:09:08 12 A Yeah, that would be borderline.

02:09:11 13 Q So above 150 is elevated in some sense.

02:09:14 14 A Correct.

02:09:14 15 Q And there is no, in the indication, upper limit on  
02:09:18 16 triglycerides, correct?

02:09:19 17 A That is correct.

02:09:20 18 Q And, in fact, at least expressly, the indication itself  
02:09:25 19 does not distinguish the cardiovascular risk reduction  
02:09:30 20 indication by baseline triglyceride level so long as it's  
02:09:34 21 above 150, correct?

02:09:35 22 A Yes.

02:09:36 23 Q Now, you've opined in this case -- and just -- we can  
02:09:40 24 scroll down, there is no limitation of use in the labeling  
02:09:43 25 that says the effect of Vascepa on cardiovascular morbidity

02:09:48 1 and mortality in patients with severe hypertriglyceridemia has  
02:09:52 2 not been determined. That limitation of use has been removed  
02:09:55 3 from the labeling, correct?

02:09:56 4 A Correct.

02:09:57 5 Q And, okay, so we go back to the indication.

02:10:00 6 So there is no overt indication that the level above  
02:10:07 7 150 matters for the REDUCE-IT indication, correct?

02:10:12 8 A Correct.

02:10:12 9 Q Though elevated triglycerides, as they go higher, can  
02:10:18 10 become a marker, one the markers of cardiovascular risk,  
02:10:22 11 correct?

02:10:23 12 A Could you repeat that?

02:10:25 13 Q As triglycerides go up, that can, itself, be a marker of  
02:10:31 14 cardiovascular risk, correct?

02:10:32 15 A That's controversial. As you might know, there is  
02:10:36 16 actually no target that's agreed on for reducing triglycerides  
02:10:41 17 per se. So that part is a little controversial.

02:10:45 18 Q You published on something called Atherogenic  
02:10:54 19 Dyslipidemia, correct?

02:10:54 20 A Using that phrase -- certainly related to that.

02:10:56 21 Q And there's another phrase, mixed dyslipidemia, too.

02:10:58 22 A Yes.

02:10:59 23 Q And both of them refer to atherogenic risk that comes  
02:11:04 24 from elevated triglycerides and/or low HDL, correct?

02:11:07 25 A Well, within that we've heard a little bit about non HDL

1 cholesterol. It's usually taken that the triglycerides per se  
2 is not the factor, it's that they indicate the presence of  
3 these remnant particles whose cholesterol that's carried is  
4 actually the damaging substance to the plaques. So  
5 triglycerides are sometimes termed a marker for the remnant or  
6 atherogenic particles.

7 Q So it's fair to say that at least some people consider  
8 elevated triglycerides a marker for cardiovascular risk,  
9 correct?

10 A That is correct.

11 Q Okay. Now, let us then look at publication that you are  
12 familiar with from REDUCE-IT. And why don't we start -- I  
13 think you had a slide that you used on the paper, DX 9.114.  
14 Is that the -- no, I got it wrong.

15 So let's try again 9.44. I'm sorry, my handwriting  
16 is not even readable by me.

17 A I was hoping you'd ask me about my publications.

18 Q 9.14 -- DDX 9.44.

19 Okay. So you've read the Bhatt 2000 article as  
20 saying that lowering triglycerides had no influence on  
21 REDUCE-IT results, correct? That's the very title of your  
22 slide, correct?

23 A That is correct.

24 Q And I think you testified, in fact, that TG lowering had  
25 nothing to do with the CV -- this cardiovascular benefit in

02:12:54 1 REDUCE-IT, correct?

02:12:55 2 A Yes.

02:12:56 3 Q And I would like to look first at the statement that you  
02:12:59 4 are quoting for support of that. And that's, I think, on the  
02:13:04 5 right hand box there. But so that we can find it some day if  
02:13:09 6 we're ever interested, that -- that's PX 272 at -- I believe  
02:13:16 7 it's -- you have it as 10. You've got two things there, but  
02:13:23 8 this one is from 10.

02:13:25 9 And why don't we blow up -- well, we can go back to  
02:13:29 10 the slide, I think it's all there on the slide, DX 9.44.

02:13:37 11 What the article says there is,

02:13:40 12 "The observed cardiovascular benefits were  
02:13:42 13 similar across baseline levels of triglycerides  
02:13:46 14 (below 150, greater or equal to 150, to below 200 and  
02:13:50 15 greater than or equal to 200 milligrams per  
02:13:53 16 deciliter.) In addition, the significantly lower  
02:13:56 17 risk of major adverse cardiovascular events with  
02:14:00 18 icosapent ethyl than with placebo appeared to occur  
02:14:05 19 irrespective of the attained triglyceride level at  
02:14:09 20 one year (greater than or equal to 150 or less than  
02:14:13 21 150 milligrams per deciliter) which suggests that the  
02:14:16 22 cardiovascular risk reduction was not associated with  
02:14:19 23 attainment of a more normal triglyceride level.

02:14:22 24 Did I read that correctly, Dr. Fisher?

02:14:24 25 A You did.

02:14:25 1 Q So what that is saying is not that TG lowering has  
02:14:29 2 nothing to do with CV benefit, but rather that the CV benefit  
02:14:33 3 applies across the range of baseline triglycerides or final  
02:14:37 4 triglyceride levels, correct?

02:14:38 5 A That the -- wait. Repeat the last part?

02:14:41 6 Q What that is saying is that the cardiovascular benefit  
02:14:45 7 applied regardless of the baseline triglyceride level where  
02:14:49 8 the patient started, or the level of triglycerides that were  
02:14:52 9 attained at year one, correct?

02:14:54 10 A Yes.

02:14:54 11 Q Okay. It doesn't say TG lowering has nothing to do with  
02:14:59 12 CV benefit, correct?

02:15:00 13 A The way it's written, that is correct.

02:15:03 14 MS. HUTTNER: Why don't we then turn to the  
02:15:05 15 actual article, PX 272, and, Mr. Brooks, if you could blow up  
02:15:12 16 beginning on the right-hand column, the first full paragraph.  
02:15:18 17 I'm sorry, it's 272, page 10. I'm not giving you the key  
02:15:24 18 information. And highlight the first and second sentences  
02:15:29 19 there.

02:15:29 20 BY MR. SIPES:

02:15:33 21 Q The authors say,

02:15:36 22 "The Mechanisms responsible for the benefit  
02:15:37 23 the icosapent ethyl" --

02:15:38 24 And let's be clear, icosapent ethyl is a  
02:15:42 25 long-winded way of saying EPA, correct?

02:15:44 1 A Correct.

02:15:44 2 Q Okay.

02:15:47 3 "Mechanisms responsible for the benefit of  
02:15:47 4 icosapent ethyl observed in REDUCE-IT are currently  
02:15:49 5 not known. The timing of the divergence of the  
02:15:52 6 Kaplan-Meier event curves suggest a delayed onset of  
02:15:55 7 benefit, which may reflect time that is needed for a  
02:15:58 8 benefit from a reduction in triglyceride levels to be  
02:16:01 9 realized or may indicate that other mechanisms are  
02:16:06 10 involved."

02:16:07 11 So the Bhatt article doesn't rule out TG  
02:16:09 12 lowering as responsible for at least part of the CV benefit,  
02:16:13 13 correct?

02:16:14 14 A It doesn't rule it out, doesn't rule it in.

02:16:16 15 Q Right. It certainly doesn't saying TG lowering has  
02:16:20 16 nothing do with the cardiovascular benefit, correct?

02:16:22 17 A Yes. This is -- this is a hypothesis that the author has  
02:16:28 18 put out.

02:16:28 19 Q And what is -- okay. Is there anything in JELIS that  
02:16:37 20 says expressly that the cardiovascular benefit to EPA applies  
02:16:42 21 regardless of baseline triglyceride level?

02:16:46 22 A Not that I recall.

02:16:48 23 Q Okay. Is there anything in JELIS that says that the  
02:16:55 24 triglyceride -- scratch that.

02:16:56 25 Is there anything in the Yokoyama paper reporting on

02:16:59 1 JELIS that says that the cardiovascular benefit applies  
02:17:02 2 regardless of the attained triglyceride level after a year?

02:17:09 3 A I don't remember it in detail enough to answer that.

02:17:14 4 Q Certainly you didn't point to anything in your testimony  
02:17:16 5 today about that, correct?

02:17:17 6 A That's correct.

02:17:18 7 Q And the baseline triglyceride levels in JELIS were just  
02:17:25 8 around 150 milligrams per deciliter, correct?

02:17:27 9 A Yeah, just above the normal range.

02:17:29 10 Q By about 1 or 2 milligrams per deciliter, correct? So it  
02:17:35 11 was essentially a normal level of triglycerides, correct?

02:17:40 12 A Near normal.

02:17:41 13 Q Okay. Now, I think one thing -- well, let me show you in  
02:17:45 14 your report -- if we can pull up your report, DX 1574, at  
02:17:53 15 paragraph 116 --

02:17:53 16 MR. SIPES: Mr. Brooks, can you give me the DX  
02:17:55 17 number? I believe it's DX 1574 at 45.

02:18:20 18 If we could blow up the last two sentences,  
02:18:25 19 Mr. Brooks.

02:18:25 20 BY MR. SIPES:

02:18:30 21 Q You wrote,

02:18:32 22 "As it pertains to patients with very high  
02:18:37 23 hypertriglyceridemia, I am not aware of any long-felt  
02:18:40 24 need for a triglyceride-lowering drug that also had a  
02:18:43 25 positive impact on cardiovascular risk. This is

02:18:46 1 because the medical focus with these patients is on  
02:18:49 2 reducing the risk of acute pancreatitis."

02:18:52 3 Do you see that?

02:18:52 4 A Yes.

02:18:53 5 Q And it is certainly true that the medical community has  
02:18:56 6 tended to overlook the cardiovascular risk in severe  
02:19:00 7 hypertriglyceridemic patients because it is secondary to the  
02:19:04 8 risk the pancreatitis, correct?

02:19:05 9 MS. HUTTNER: Objection, Your Honor, no  
02:19:06 10 foundation at this point.

02:19:08 11 MR. SIPES: I'm asking him as an expert.

02:19:10 12 THE COURT: The objection is overruled. He did  
02:19:12 13 testify to the former. So, I think it's fair to follow-up on  
02:19:16 14 the basis.

02:19:18 15 THE WITNESS: Okay. Repeat the question,  
02:19:19 16 please.

02:19:20 17 BY MR. SIPES:

02:19:20 18 Q It is correct, is it not, that the cardiovascular risk in  
02:19:24 19 patients with severe hypertriglyceridemia has tended to be  
02:19:27 20 overlooked by the medical community because they are focused  
02:19:31 21 on the risk of pancreatitis?

02:19:33 22 A Well, that certainly takes precedence clinically. But I  
02:19:36 23 also, in reviewing ATP III in the last few days, it does have  
02:19:41 24 a line in there that the cardiovascular risk of severe  
02:19:47 25 hypertriglyceridemia as an isolated lipid disorder is not

02:19:52 1 associated with a particularly strong signal on risk.

02:19:57 2 Q So even ATP III is sort of suggesting that it's the risk  
02:20:04 3 of pancreatitis, medical community, you should be focused on,  
02:20:07 4 not the cardiovascular risk.

02:20:08 5 A Right. In 2008, that was the ruling guidelines.

02:20:12 6 Q And you're not aware of any drug, putting Vascepa aside,  
02:20:17 7 that has been approved for reduction of cardiovascular risk in  
02:20:22 8 severe hypertriglyceridemic patients through TG lowering --  
02:20:27 9 let me phrase that more clearly.

02:20:29 10 You're not aware of any drug approved for the  
02:20:31 11 treatment of severe hypertriglyceridemia that has been shown  
02:20:34 12 to have a cardiovascular benefit in severe  
02:20:38 13 hypertriglyceridemic patients putting Vascepa aside.

02:20:51 14 A That is correct.

02:20:51 15 Q Now, you spent a lot of time today going over Amarin's  
02:21:10 16 statements about JELIS, correct?

02:21:13 17 A Yes.

02:21:13 18 Q And they were mostly in the 2013 and 2014 time period,  
02:21:17 19 correct?

02:21:18 20 A Correct.

02:21:18 21 Q And they all had to do with Amarin's pursuit of the  
02:21:25 22 so-called ANCHOR indication, correct?

02:21:27 23 A Yes.

02:21:28 24 Q And that followed on the ANCHOR study, correct?

02:21:31 25 A Yes.

02:21:32 1 Q You did not cite any published literature describing  
02:21:40 2 JELIS as -- citing to JELIS for support for treatment  
02:21:44 3 guidelines on the reduction of cardiovascular risk by the  
02:21:48 4 administration of EPA, correct?

02:21:50 5 A That is correct.

02:21:53 6 Q And the Amarin documents that you cited, do you know what  
02:22:01 7 indication that -- the ANCHOR indication had to do with? Do  
02:22:05 8 you know what the ANCHOR indication was?

02:22:08 9 A Well, this was a trial in patients with the type of lipid  
02:22:15 10 profile that was being studied in REDUCE-IT.

02:22:19 11 Q Well, we'll come back to that.

02:22:21 12 What was the indication, the ANCHOR indication? Do  
02:22:26 13 you know what the ANCHOR indication was?

02:22:28 14 A Well, the study was to look at -- over a more extended  
02:22:32 15 period of time than the MARINE trial, of 4 grams of Vascepa on  
02:22:38 16 the lipoprotein profile of a population that had triglyceride  
02:22:44 17 levels between 150 and 500.

02:22:47 18 Q Do you believe the ANCHOR study was longer than the  
02:22:50 19 MARINE study?

02:22:51 20 A Yes.

02:22:51 21 MR. SIPES: Okay. Why don't we pull up just to  
02:22:53 22 get to the bottom of some of this, DDX 2.60. This is a  
02:23:01 23 demonstrative the defendants have used previously in this  
02:23:04 24 case.  
02:23:04 25

02:23:04 1 BY MR. SIPES:

02:23:05 2 Q This is the ANCHOR indication, is it not. This is  
02:23:08 3 referring to the SNDA for the ANCHOR indication, correct?

02:23:14 4 A Yes.

02:23:15 5 MS. HUTTNER: Your Honor, is this -- I don't --  
02:23:18 6 I don't know if perhaps the wrong slide is up, but I don't see  
02:23:21 7 anything on this that pertains to ANCHOR, maybe I'm missing  
02:23:26 8 it.

02:23:27 9 MR. SIPES: Do I have the wrong -- DDX 2.60?  
02:23:27 10 Oh, I'm sorry, did I --

02:23:30 11 THE COURT: Oh, right, this is the press  
02:23:31 12 release.

02:23:32 13 MR. SIPES: Let's go to 2.60.

02:23:35 14 THE COURT: Ms. Huttner, you got it right. If  
02:23:39 15 there's objection, it's sustained.

02:23:41 16 MS. HUTTNER: I scored one.

02:23:41 17 MR. SIPES: My eyes are not what it they used to  
02:23:44 18 be. I apologize, Your Honor. So 2.60.

02:23:44 19 BY MR. SIPES:

02:23:46 20 Q Here we are. This is concerning the ANCHOR SNDA which  
02:23:49 21 was the subject of all of these documents you were talking  
02:23:53 22 about with regard to the act on, correct, Dr. Fisher?

02:23:55 23 A Yes.

02:23:55 24 Q And I think, first, if you'll look, you'll see to support  
02:23:58 25 this indication you submitted the results from the ANCHOR

02:24:00 1 study, correct?

02:24:01 2 A Correct.

02:24:04 3 Q And if you read down, the primary endpoint was the  
02:24:07 4 percent change in TG levels from baseline in week 12.

02:24:11 5 A Correct.

02:24:12 6 Q So it's 12-week study just like MARINE, correct,  
02:24:16 7 Dr. Fisher?

02:24:16 8 A Yes, as stated here. I'm sorry I was confused.

02:24:20 9 Q No, that's quite. All right. The point is ANCHOR was a  
02:24:23 10 very different study than REDUCE-IT, correct?

02:24:25 11 A Yes.

02:24:26 12 Q REDUCE-IT was a 5-year study.

02:24:30 13 A Correct.

02:24:30 14 Q That involved 8,000 patients.

02:24:33 15 A Right.

02:24:33 16 Q Much, much, bigger than ANCHOR, correct?

02:24:37 17 A Yes.

02:24:37 18 Q And there's no suggesting in here that ANCHOR involved  
02:24:40 19 any patients who developed triglycerides over 500, correct?

02:24:44 20 A Right. The entry criteria was fasting, TG level below  
02:24:53 21 500 was one of the parameters.

02:24:55 22 Q And, in fact, FDA said in reviewing the MARINE indication  
02:25:00 23 that it wouldn't look to the ANCHOR indication for efficacy  
02:25:03 24 because it was a different patient population, porrect?

02:25:06 25 A Yes.

02:25:06 1 Q And the indication for ANCHOR was patients with mixed  
02:25:12 2 dyslipidemia and coronary heart disease or coronary heart  
02:25:21 3 disease risk equivalent, correct?

02:25:25 4 That's the indication. Do you see that?

02:25:28 5 A Yeah. With mixed dyslipidemia and coronary heart disease  
02:25:32 6 or coronary heart disease risk equivalent.

02:25:35 7 Q So ANCHOR is a lot more like the patient population in  
02:25:40 8 JELIS than MARINE is, correct?

02:25:42 9 A Yes.

02:25:44 10 Q Okay. Although even ANCHOR was a higher TG group than  
02:25:51 11 JELIS, correct?

02:25:52 12 A Yes, because the -- it says the baseline fasting TG level  
02:26:00 13 was equal or greater than 185.

02:26:04 14 Q So you can see this ladder in which Amarin is developing  
02:26:08 15 evidence on the administration of 4 grams per day of EPA to  
02:26:13 16 increasingly higher groups of patients with increasingly  
02:26:17 17 higher triglyceride levels, correct?

02:26:20 18 A Yes.

02:26:20 19 Q And it's in that context, well after 2008, that these  
02:26:26 20 Amarin statements that you're pointing to were made, correct?

02:26:30 21 A Yes, well after 2008.

02:26:32 22 Q Right. And, importantly, these statements that you've  
02:26:36 23 been pointing to are after both MARINE and ANCHOR, studies  
02:26:41 24 Amarin itself did on 4 grams per day of EPA, correct?

02:26:45 25 A Yes.

02:26:46 1 Q And, now, you did not identify this morning that you  
02:26:55 2 yourself have published -- or been an author on published  
02:27:01 3 guidance on dealing with cardiovascular risk that in fact  
02:27:06 4 found JELIS not to be evidence of a reduction in  
02:27:10 5 cardiovascular risk, correct?

02:27:11 6 A I think that was included in a consensus paper in which  
02:27:17 7 my role was to write about basic science mechanisms by which  
02:27:24 8 triglycerides might be operating in atherosclerosis. But, I  
02:27:28 9 did not have direct input into the -- we'll say the clinical  
02:27:35 10 recommendations.

02:27:36 11 MR. SIPES: Well, let's take look at it.

02:27:38 12 Mr. Brooks, if you could pull up PX 373.

02:27:38 13 BY MR. SIPES:

02:27:45 14 Q This is a paper from the *European Heart Journal* published  
02:27:49 15 in 2011, correct?

02:27:51 16 A Yes.

02:27:51 17 Q And it's entitled, "Triglyceride-Rich Lipoproteins and  
02:27:55 18 High Density Lipoprotein Cholesterol in Patients At High Risk  
02:28:00 19 of Cardiovascular Disease, Evidence and Guidance For  
02:28:04 20 Management."

02:28:05 21 Do you see that?

02:28:06 22 A I do.

02:28:06 23 MS. HUTTNER: Excuse me, Your Honor, is -- it's  
02:28:08 24 not -- I can't see on the screen where Mr. -- is there a  
02:28:12 25 possibility you can enlarge that, Mr. Sipes?

02:28:14 1 MR. SIPES: That was the title.

02:28:15 2 MS. HUTTNER: Oh, okay.

02:28:17 3 MR. SIPES: But we can make it bigger.

02:28:18 4 BY MR. SIPES:

02:28:19 5 Q So this is an article -- and if you look in the list of  
02:28:23 6 authors, Edward Fisher, that's you.

02:28:25 7 A There I am.

02:28:26 8 Q So you're one the authors on this paper, correct?

02:28:29 9 A Yeah, left out my middle initial.

02:28:31 10 Q And you're writing on behalf of number of experts for the  
02:28:35 11 European Atherosclerosis Society Consensus Panel, correct?

02:28:40 12 A I was a member of that group, yes.

02:28:42 13 Q And that's an august body, correct?

02:28:49 14 A Yes.

02:28:50 15 MR. SIPES: And I would move PX 373 into  
02:28:53 16 evidence.

02:28:55 17 MS. HUTTNER: No objection, Your Honor.

02:28:56 18 THE COURT: 373 is admitted.

02:28:56 19 (Plaintiff's Exhibit 373 received in  
02:28:56 evidence.)

02:28:59 20 MR. SIPES: So let's get ourselves oriented in  
02:29:02 21 time. Mr. Brooks, if you could blow up where it says received  
02:29:06 22 25 November 2010.

02:29:06 23 BY MR. SIPES:

02:29:10 24 Q So this paper, these -- this guidance was submitted in  
02:29:15 25 November 2010, correct?

02:29:18 1 A Yes.

02:29:18 2 Q Before MARINE and before ANCHOR, correct?

02:29:21 3 A Yes.

02:29:24 4 MR. SIPES: And, Mr. Brooks, if you would turn  
02:29:26 5 to page PX 373-0016. Under Author Contribution, if you could  
02:29:44 6 blow up Author Contribution. And then if you could just  
02:29:48 7 highlight the very last sentence.

02:29:48 8 BY MR. SIPES:

02:29:58 9 Q Dr. Fisher, it states under Author Contribution,

02:30:01 10 "All members of the EAS consensus panel were  
02:30:04 11 involved in the writing of the manuscript and  
02:30:07 12 approved the final manuscript before submission."

02:30:11 13 Do you see that?

02:30:11 14 A That's what it says.

02:30:12 15 Q And that's true.

02:30:13 16 A Yes, but the way consensus panels operate that's -- it  
02:30:20 17 may not be clear to you, at least in the medical field, we are  
02:30:27 18 assigned the topics that we have particular expertise in.

02:30:33 19 And, as I have mentioned before, that my  
02:30:36 20 contribution was to write about potential mechanisms based on  
02:30:40 21 animal and cell models by which triglycerides can be causing  
02:30:44 22 increased risk.

02:30:46 23 The more clinically oriented expert members such as  
02:30:51 24 Henry Ginsberg, in particular, who was the lead investigator  
02:30:56 25 on ACCORD, by the way, they had the responsibility of

02:31:00 1 recommending what implementation or what the implications, the  
02:31:05 2 clinical implications of what we reviewed.

02:31:08 3 So although it is -- I don't disavow, this is a  
02:31:12 4 factual statement, at the final end, those of us who felt not  
02:31:20 5 as expert in one area or the other did not object -- we had no  
02:31:25 6 basis to object or really opine on the merit of some of the  
02:31:28 7 recommendations that were made, just the way Henry Ginsberg  
02:31:32 8 did not sit and criticize in a meaningful way what we wrote up  
02:31:36 9 in the basic science part.

02:31:38 10 So it's a little bit of the horse trading operation.  
02:31:42 11 But that's inevitable in all consensus panels that I've been  
02:31:47 12 aware of.

02:31:48 13 But I do not dispute what this statement says.

02:31:51 14 MR. SIPES: Mr. Brooks, if you could play 163, 3  
02:31:54 15 through ten.

02:31:55 16 (Deposition video recording played.)

02:32:20 17 BY MR. SIPES:

02:32:21 18 Q That's a shorter answer, correct?

02:32:22 19 A Yes. I seem to have my head up higher today than in my  
02:32:28 20 deposition.

02:32:29 21 Q And you felt that the committee was a group of  
02:32:32 22 well-respected clinicians and scientists, correct?

02:32:35 23 A Yes.

02:32:35 24 Q And the effort in this publication was to provide  
02:32:39 25 guidance to clinicians in managing cardiovascular disease.

02:32:43 1 A It was to evaluate the available evidence and to  
02:32:46 2 formulate some -- try to distill them into something that  
02:32:50 3 would be valuable to clinicians.

02:32:54 4 MR. SIPES: Mr. Brooks, why don't we turn to  
02:32:56 5 what the guidance was so PX 373 at 13. And if you could blow  
02:33:02 6 up Figure 6, both the figure and the legend.

02:33:05 7 And I'm hoping this remains readable.

02:33:07 8 But Figure 6 purports to be the proposed  
02:33:10 9 algorithm for the management of higher risk individuals with  
02:33:13 10 elevated triglycerides and/or low HDL cholesterol at LDL  
02:33:19 11 cholesterol goal.

02:33:19 12 BY MR. SIPES:

02:33:21 13 Q Do you see that?

02:33:21 14 A Yes.

02:33:21 15 Q Algorithm now has taken on a more ugly meaning, but back  
02:33:27 16 then you were really saying this is a flow chart to follow  
02:33:30 17 with your decision making as a clinician, right?

02:33:30 18 A Proposed.

02:33:31 19 Q And when you refer to patients at LDL cholesterol goal,  
02:33:36 20 you're assuming people that either they're on a statin or have  
02:33:40 21 otherwise have achieved their LDL cholesterol goal, correct?

02:33:43 22 A Yes.

02:33:44 23 Q You're saying what do we do now to manage the residual  
02:33:47 24 risk, the cardiovascular risk that remains even on patients  
02:33:48 25 who have achieved goals with statins, correct?

02:33:51 1 A Yes.

02:33:52 2 Q And this idea of residual cardiovascular risk, that is a  
02:33:56 3 serious issue in the western world, correct?

02:33:58 4 A Yes, it is.

02:33:59 5 Q In fact, even after LDL-C goal is attained with statins,  
02:34:04 6 that eliminates maybe one-third of cardiovascular effects,  
02:34:08 7 correct?

02:34:08 8 A It's gone up. Those studies done in the era when statins  
02:34:14 9 were less potent, and now that with Rosuvastatin and the PCSK9  
02:34:21 10 inhibitors, I think we're approaching above 40 percent. But  
02:34:25 11 not to split hairs, it's at least half of the risk is still  
02:34:29 12 residual.

02:34:30 13 Q Statin therapy is much better today than it was 20 years  
02:34:33 14 ago.

02:34:34 15 A Definitely.

02:34:34 16 Q Which, of course, is one of the differences between  
02:34:37 17 REDUCE-IT and JELIS is the level of statin therapy in the two  
02:34:41 18 patient groups, correct?

02:34:42 19 A Yes. Over time, yes. That was inevitable.

02:34:47 20 Q In any event, with regard to residual risk in Figure 6,  
02:34:50 21 the first step is to intensify lifestyle management, address  
02:34:50 22 secondary causes, check compliance, correct?

02:34:56 23 A Yes.

02:34:56 24 Q But then if there's insufficient improvement one, thing  
02:35:00 25 is consider adding niacin or fibrate is the recommendation,

02:35:03 1 correct?

02:35:04 2 A Yes.

02:35:04 3 MS. HUTTNER: Your Honor, I object to this as  
02:35:07 4 beyond the scope. I mean, this is going to an issue that came  
02:35:10 5 up during the infringement portion of the case.

02:35:12 6 You may recall that there was a difference  
02:35:15 7 between Dr. Budoff's testimony that he started patients on  
02:35:19 8 triglycerides -- on -- I'm sorry, on Vascepa only after a  
02:35:23 9 period of lifestyle modifications, and there was testimony in  
02:35:29 10 opposition to that by Dr. Sheinberg, that he is talking --  
02:35:35 11 that he typically puts patients on statins -- I'm sorry, on  
02:35:39 12 triglyceride-lowering drugs right away if they're in that very  
02:35:43 13 high category.

02:35:44 14 So I don't know where this is going, but to the  
02:35:47 15 extent that, you know, it's going to the infringement  
02:35:50 16 question, I'm just raising the flag here. I --

02:35:53 17 MR. SIPES: Your Honor, we'll get to that later.  
02:35:54 18 She did bring up some questions about diet, but that's not  
02:35:58 19 where this is going.

02:35:59 20 I'm not accustomed to having to say where I'm  
02:35:59 21 going in a cross-examination, but this goes to whether or not  
02:36:02 22 JELIS was perceived as addressing residual risk, just to  
02:36:05 23 explain it to Ms. Huttner.

02:36:07 24 MS. HUTTNER: Thank you.

25 ///

02:36:08 1 BY MR. SIPES:

02:36:08 2 Q Dr. Fisher, try to pay no attention to when we have these  
02:36:12 3 discussions.

02:36:13 4 A I would like to know where you're going.

02:36:15 5 THE COURT: It's giving you an indication of  
02:36:16 6 where this is headed, so this is helpful.

02:36:16 7 THE WITNESS: Pardon?

02:36:19 8 THE COURT: Mr. Sipes is giving you an  
02:36:20 9 indication of where it this headed so this is very helpful.

02:36:24 10 THE WITNESS: That's right.

02:36:25 11 BY MR. SIPES:

02:36:26 12 Q So what is recommended in Figure 6 for addressing  
02:36:29 13 residual atherogenic risk is niacin or fibrate, correct?

02:36:34 14 A That is correct.

02:36:34 15 Q And in the legend it says high dose omega-3 fatty acids,  
02:36:40 16 fibrate or niacin, may be considered if the patient has very  
02:36:44 17 high TG -- has very high TG to prevent pancreatitis, correct?

02:36:47 18 A That is correct.

02:36:48 19 Q But in terms of addressing atherogenic risk, what is  
02:36:55 20 recommended is just niacin or fibrate, correct?

02:36:58 21 A Let me just look at that footnote -- is that footnote C?

02:37:12 22 Q I could read it for you. Footnote 3 says,

02:37:15 23 "Based on clinical outcome data and safety

02:37:15 24 considerations for combination statin fibrate

02:37:23 25 therapy, fenofibrate is the preferred fibrate. This

02:37:23 1           fibrate may have particular value in patients with  
02:37:28 2           Type 2 diabetes mellitus and mild to moderate  
02:37:28 3           retinopathy."

02:37:32 4                     Does that help?

02:37:33 5       A     Yes, it does.

02:37:33 6       Q     So that makes it clear that for purposes of addressing  
02:37:36 7     pancreatitis, omega-3 is mentioned, but the recommendation for  
02:37:40 8     addressing atherogenic dyslipidemia, that is, cardiovascular  
02:37:46 9     risk, the recommendation is niacin or fibrate, correct?

02:37:52 10    A     Yes.

02:37:52 11    Q     Then, if we go on to PX 373-16, there's a box that says  
02:38:02 12    Key Messages. For a lot of physicians it's helpful to have a  
02:38:08 13    little box that says Key Messages, correct?

02:38:11 14    A     Definitely.

02:38:11 15    Q     It's a bit like FDA's little black box warnings, they  
02:38:11 16    know sometimes you've really got to get a clinician's opinion,  
02:38:11 17    correct?

02:38:17 18    A     Yes.

02:38:18 19    Q     And here, to get the physician's opinion, you have this  
02:38:20 20    bottom bullet under Key Messages.

02:38:22 21                     "Aiding niacin or fibrate, or intensifying  
02:38:26 22           LDL-C lowering are suggested options for correction  
02:38:30 23           of atherogenic dyslipidemia," correct?

02:38:33 24    A     Yes.

02:38:33 25    Q     You do not recommend either EPA or an omega-3 fatty acid

02:38:39 1 for addressing atherogenic dyslipidemia, correct?

02:38:43 2 A That is correct.

02:38:44 3 Q Yes. And so -- and that reference to atherogenic  
02:38:46 4 dyslipidemia, that's this residual cardiovascular risk left  
02:38:49 5 after a statin, correct?

02:38:51 6 A Yes. These are those remnant particles that are thought  
02:38:55 7 to be of significance.

02:39:00 8 MR. SIPES: Now, if we go to the left-hand  
02:39:02 9 column, the last paragraph above Box 6 -- Mr. Brooks, if you  
02:39:08 10 would blow up just the last couple sentences.

02:39:08 11 BY MR. SIPES:

02:39:14 12 Q The panel writes,

02:39:16 13 "The panel also recognizes the limitations of  
02:39:19 14 the current evidence base for fibrates, niacin, and  
02:39:23 15 omega-3 fatty acids, including the lack of hard  
02:39:25 16 outcome data for statin niacin and statin omega-3  
02:39:31 17 fatty acid combination therapies. Clearly, there is  
02:39:33 18 a need for well-defined trials to evaluate the  
02:39:36 19 efficacy and safety of these therapeutic combinations  
02:39:39 20 in high risk patients at LDL-C goal with elevated  
02:39:43 21 triglycerides and/or low HDL-C."

02:39:46 22 Did I read that correctly?

02:39:47 23 A You did.

02:39:48 24 Q And it's not that the panel was unaware of JELIS,  
02:39:53 25 correct?

02:39:54 1 A It had been published in 2007.

02:39:59 2 Q Well, it's more than that.

02:40:00 3 MR. SIPES: Mr. Brooks, if you could turn to  
02:40:03 4 PX 373 on page 22 and blow up reference 224.

02:40:11 5 Reference 224 in your 2011 consensus panel  
02:40:17 6 publication, is the JELIS publication, correct?

02:40:19 7 A Correct.

02:40:20 8 Q So this panel cites to JELIS.

02:40:23 9 A Could we see in the article what is actually said about  
02:40:26 10 JELIS. Do you have that in the article itself where JELIS is  
02:40:30 11 discussed?

02:40:31 12 Q Is it not discussing what it's recommending and whether  
02:40:34 13 it views adequate evidence?

02:40:36 14 A No, what I mean is, in general, any one study does not  
02:40:43 15 wind up becoming a guideline, and I'm not -- I'm not  
02:40:48 16 remembering this since I didn't write, except a small piece of  
02:40:52 17 the basic science, in what context JELIS was raised in this  
02:40:57 18 study.

02:40:58 19 Besides your noting that the committee was aware of  
02:41:02 20 it, and yet in that little box they mention it, it doesn't  
02:41:06 21 mean it had a negative view. It could have been brought up in  
02:41:09 22 the context that this is a promising study that deserves a  
02:41:13 23 further investigation.

02:41:16 24 That would be a lot different message to a person  
02:41:19 25 than saying JELIS is rubbish and doesn't prove anything.

02:41:21 1 Q But you're not aware of this paper describing JELIS as  
02:41:25 2 promising, correct?

02:41:26 3 A I'm not aware of any -- anything concerning at this point  
02:41:32 4 how it was discussed in the context of the paper.

02:41:34 5 Q And in your testimony you didn't discuss this paper. In  
02:41:37 6 testimony this morning you didn't discuss PX 373, correct?

02:41:40 7 A That is correct.

02:41:41 8 Q And, in fact, you didn't discuss any paper that described  
02:41:45 9 JELIS as promising, correct?

02:41:48 10 A The REDUCE-IT paper.

02:41:49 11 Q Well -- I'm sorry, yeah. The Amarin REDUCE-IT papers is  
02:41:54 12 what you relied on, correct? Amarin's own statements,  
02:41:57 13 correct?

02:41:57 14 A Yes.

02:41:58 15 Q Okay. And when you were treating -- when you were  
02:42:10 16 practicing medicine, you prescribed Lovaza as you said,  
02:42:13 17 correct?

02:42:13 18 A Yes.

02:42:14 19 Q And that was true in 2008, correct?

02:42:16 20 A Correct.

02:42:16 21 Q And JELIS didn't make you switch and find an EPA only  
02:42:20 22 product, correct?

02:42:20 23 A Well, Epadel is not -- is still not available in the  
02:42:24 24 United States.

02:42:24 25 Q And are you aware about -- did you research and look for

02:42:28 1 EPA-only supplements?

02:42:30 2 A I looked at that time for over-the-counter supplements  
02:42:36 3 that were considered to be of a high quality but had both EPA  
02:42:43 4 and DHA in them at that time.

02:42:51 5 Q Now, you, yourself, take a fish oil supplement for  
02:42:57 6 cardiovascular health, correct?

02:42:59 7 A I do, and whatever else it does.

02:43:02 8 Q And you told me at deposition that the supplement you  
02:43:06 9 take is a CVS brand supplement, it has about 180 milligrams  
02:43:10 10 EPA and 120 milligrams DHA, correct?

02:43:14 11 A Yes.

02:43:14 12 Q And so the fish oil supplement that you take for  
02:43:17 13 cardiovascular risk, for cardiovascular health, is a mixture  
02:43:24 14 of EPA and DHA, correct?

02:43:24 15 A It is.

02:43:25 16 Q So even in 2019, for your own health, you've not been  
02:43:29 17 motivated to use an EPA only product, correct?

02:43:33 18 A No because my triglycerides are not only normal, but I'm  
02:43:36 19 also on a statin.

02:43:38 20 Q And you told me at your deposition that you believe that  
02:43:41 21 there is not enough evidence to say that there are CV benefits  
02:43:46 22 to EPA alone rather than a mixture of EPA and DHA, correct?

02:43:51 23 A If you said I said it, I'm surprised. If you could just  
02:43:58 24 repeat what you recall that I said.

02:44:01 25 MR. SIPES: Mr. Brooks, if you could place 133,

02:44:04 1 9 to 14.

02:44:05 2 (Deposition video recording played.)

02:44:31 3 BY MR. SIPES:

02:44:32 4 Q Of course, we have REDUCE-IT now, correct?

02:44:34 5 A Correct.

02:44:34 6 Q And we even have more information now, correct?

02:44:37 7 A Yes. And this is the second study.

02:44:39 8 As I said just before, that a single study is not,  
02:44:46 9 in my opinion, conclusive evidence. And so the fact that  
02:44:50 10 there were now two studies, and the date on the deposition, of  
02:44:55 11 course, was before REDUCE-IT was published, the fact that  
02:44:59 12 there were two studies that got similar results in that EPA,  
02:45:05 13 purified EPA had a benefit, yes, my opinion has changed.

02:45:10 14 Q Dr. Fisher, let's just be clear on something. Your  
02:45:13 15 deposition was on July 2nd, 2019.

02:45:16 16 A Yes.

02:45:17 17 Q The REDUCE-IT results were published in November of 2018,  
02:45:22 18 correct?

02:45:22 19 A Yeah.

02:45:24 20 Q In fact, you've discussed the REDUCE-IT results in your  
02:45:28 21 reports, correct?

02:45:28 22 A Yeah. I'm getting tired here.

02:45:30 23 Q Right. So your comment that you didn't think there was  
02:45:33 24 sufficient evidence that there are cardiovascular limits to  
02:45:39 25 EPA alone rather than the mixture of EPA and DHA, that's post

02:45:41 1 REDUCE-IT, correct?

02:45:41 2 A That is correct.

02:45:42 3 Q But the key point is it was prior to the failure of the  
02:45:46 4 STRENGTH trial, correct?

02:45:47 5 MS. HUTTNER: Your Honor, now I do object. The  
02:45:49 6 STRENGTH trial was a trial of an un -- of another drug which  
02:45:53 7 is not involved in this case that is called Epanova, and  
02:45:58 8 was -- the STRENGTH trial he's referring to was an outcome  
02:46:02 9 study involving Epanova which is not -- nothing to do with the  
02:46:06 10 issues in this case.

02:46:09 11 I don't -- I -- it's just well beyond the scope  
02:46:13 12 of the --

02:46:14 13 MR. SIPES: Your Honor, actually, the STRENGTH  
02:46:16 14 trial was discussed in his deposition, and it's not outside  
02:46:21 15 the scope. The comparison is between the cardiovascular  
02:46:24 16 benefits of EPA alone versus various mixtures.

02:46:27 17 And, in fact, there's discussions of Epanova and  
02:46:29 18 the fact it's yet another mixture of EPA and DHA in the  
02:46:33 19 reports and in this case.

02:46:35 20 They are maintaining here that somehow it was  
02:46:38 21 obvious to use EPA alone. In fact, other than Amarin, in  
02:46:43 22 cardiovascular health here, everyone has been looking at  
02:46:46 23 various assortments of mixtures and failing.

02:46:49 24 And I understand why they want to keep it out,  
02:46:51 25 but it's pretty significant that AstraZeneca just spent five

02:46:57 1 plus years running a 10,000 patient trial on a mixture and it  
02:47:01 2 failed on Monday.

02:47:04 3 THE COURT: So the objection is that the  
02:47:05 4 reference to this other study is irrelevant because this other  
02:47:09 5 study focuses -- I'm trying to understand the objection  
02:47:13 6 because if Dr. Fisher testified to this other study in his  
02:47:16 7 deposition --

02:47:17 8 MS. HUTTNER: Well, he was asked a question  
02:47:19 9 about this other study. He didn't -- to my recollection,  
02:47:22 10 anyway, he didn't discuss the STRENGTH trial in his expert  
02:47:25 11 report, nor did he testify about the STRENGTH trial in his  
02:47:30 12 testimony, nor did he make any -- offer any opinion about  
02:47:35 13 whether or not it would be -- you know, it would be obvious to  
02:47:38 14 make to have a mixture of DHA or EPA versus a straight EPA  
02:47:43 15 product. That was raised with Dr. Heinecke yesterday.

02:47:43 16 MR. SIPES: But --

02:47:43 17 MS. HUTTNER: So in terms of --

02:47:43 18 THE COURT: Hang on.

02:47:46 19 MS. HUTTNER: Let me finish, Mr. Sipes.

02:47:48 20 In terms of what this witness has testified to,  
02:47:52 21 he has opined that based on the JELIS, which is a pure EPA  
02:47:55 22 study, that one would expect the same active ingredient EPA in  
02:48:00 23 the REDUCE-IT trial similarly to show cardiac benefits.

02:48:04 24 He didn't testify about any leap from a mixture  
02:48:07 25 of DHA and EPA, he's strictly comparing between EPA studies.

02:48:12 1 So the STRENGTH trial, which, by the way,  
02:48:14 2 literally failed -- it was announced in the press the date we  
02:48:19 3 began trial, what it has to do with anything, I don't know.

02:48:23 4 MR. SIPES: Well, I can --

02:48:23 5 THE COURT: So is the -- I'm trying to  
02:48:27 6 understand the reason for the reference to this other trial.  
02:48:30 7 Is it STRENGTH, S-t-r --

02:48:33 8 MS. HUTTNER: It's an acronym of some sort.

02:48:36 9 MR. SIPES: S-t-r-e-n-g-t-h.

02:48:36 10 MS. HUTTNER: I don't recall what it stands for.  
02:48:39 11 But it involves, as I said, a drug called Epanova which is an  
02:48:43 12 AstraZeneca drug that is like Lovaza, it's a slightly  
02:48:48 13 different mixture of DHA and EPA.

02:48:51 14 It's not discussed in Dr. Fisher's report, he  
02:48:53 15 didn't discuss it in his testimony on the stand today, and it  
02:48:57 16 really has nothing to do with the opinions that he is offering  
02:49:00 17 in this case which simply are that there's no basis for  
02:49:06 18 finding nonobviousness based on the secondary evidence  
02:49:09 19 discussed by Dr. --

02:49:11 20 THE COURT: All right. Hang on a moment. I  
02:49:12 21 know, Mr. Sipes, you are very eager to respond, but I'm just  
02:49:16 22 trying to understand where you're headed here.

02:49:17 23 So Dr. Fisher's testimony is there's not enough  
02:49:21 24 evidence to say that there's cardiovascular benefits to EPA  
02:49:24 25 rather than a mixture of EPA and DHA. That's established. He

1 testified -- he testified to that in his deposition. He  
2 reiterated that here.

3 So, Mr. Sipes, are you trying to challenge that  
4 testimony that there's not enough evidence by pointing out to  
5 other evidence?

6 MR. SIPES: At the time he has opined that JELIS  
7 rendered REDUCE-IT expected rather than unexpected.

8 THE COURT: Right.

9 MR. SIPES: In fact, which we'll get into, he  
10 also opined in deposition, and it's classic impeachment, that  
11 JELIS would have been -- provided a reasonable expectation of  
12 success with STRENGTH as well, but, in fact STRENGTH has  
13 failed which shows that JELIS is not a good precedent for  
14 predicting the outcome of cardiovascular outcome trials.

15 MS. HUTTNER: Your Honor, first of all --

16 MR. SIPES: That's classic -- it's absolutely  
17 related to his opinion where he's saying JELIS predicted  
18 REDUCE IT. When he said JELIS predicted STRENGTH, not so easy  
19 to predict these trials, I should be able to draw that  
20 testimony out.

21 THE COURT: Where is that testimony in his  
22 deposition?

23 MR. SIPES: It's on page 157 to 158, and we  
24 could play it if you want, you can see what he says.

25 THE COURT: Well, let me read the testimony.

02:50:40 1 MR. SIPES: Okay.

02:50:40 2 THE COURT: Not you reading it, let me read it.

02:50:43 3 MR. SIPES: No, no. So if you begin on 157, and  
02:50:48 4 the predicate here is that JELIS patients had DHA in their  
02:50:52 5 diet. You can read 157 at 21, to 158 at 9.

02:51:04 6 MS. HUTTNER: Your Honor, do you want this on  
02:51:06 7 screen?

02:51:06 8 THE COURT: Well, you argued your position for  
02:51:08 9 Dr. Fisher so I assume you know what you testified to. I  
02:51:11 10 don't have an issue with putting it on the screen if it's  
02:51:14 11 easier for everyone.

02:51:18 12 MR. SIPES: We have a hard copy if you would  
02:51:20 13 like it, Your Honor.

02:51:21 14 THE COURT: I can read this.

02:51:24 15 MS. HUTTNER: I'm sorry, the reference was to  
02:51:26 16 which page and line?

02:51:28 17 THE COURT: 157 at line 21, to 158, line 9.

02:51:34 18 MR. SIPES: Yep.

02:51:35 19 MS. HUTTNER: Thank you, Your Honor.

02:52:02 20 THE COURT: All right. So it was Mr. Fisher who  
02:52:05 21 brought up the reference to the STRENGTH trial, and,  
02:52:08 22 Mr. Sipes, you're saying that because he testified to this  
02:52:10 23 you're entitled to address --

02:52:12 24 MR. SIPES: And --

02:52:12 25 THE COURT: -- his testimony?

02:52:13 1 MR. SIPES: And also because it is directly  
02:52:15 2 impeachment on his opinion that JELIS made it expected that  
02:52:20 3 REDUCE-IT would turn out favorably because he also testified  
02:52:23 4 that JELIS meant that STRENGTH would turn out favorably and,  
02:52:28 5 of course, it did not, which makes our point that JELIS really  
02:52:32 6 isn't a way to predict what's going to happen with these  
02:52:35 7 cardiovascular --

02:52:37 8 THE COURT: I understand the argument and the  
02:52:37 9 inference is strong here. Ms. Huttner, what's your response?

02:52:40 10 MS. HUTTNER: Well, Your Honor, first of all, if  
02:52:42 11 you look at the transcript on page 157 it was actually --  
02:52:46 12 actually earlier on page 156, it's Mr. Sipes who brought up  
02:52:52 13 the STRENGTH trial.

02:52:54 14 He asked, "Are you aware that AstraZeneca is  
02:52:56 15 sponsoring the STRENGTH trial to look at cardiovascular  
02:53:00 16 outcomes using 4 grams of Epanova?"

02:53:03 17 And then he's -- Dr. Fisher is refreshed, and  
02:53:07 18 then he's asked a question, "Do you have an expectation about  
02:53:10 19 whether or not STRENGTH will show cardiovascular benefits?"

02:53:13 20 And he says in response -- he simply says,  
02:53:17 21 "This will be a very interesting study to follow."

02:53:19 22 And then he asks a question about, "What are the  
02:53:21 23 selection criteria of STRENGTH?"

02:53:24 24 He did not -- I mean, the point is he did not  
02:53:27 25 offer any opinions in his report related to the STRENGTH

02:53:30 1 trial.

02:53:30 2 I do not believe he is familiar with the  
02:53:33 3 parameters, as evidenced by his question on the record to  
02:53:36 4 Mr. Sipes, that he's familiar with the details pertaining to  
02:53:40 5 that study, and also --

02:53:40 6 MR. SIPES: He --

02:53:41 7 MS. HUTTNER: And also -- excuse me.

02:53:42 8 Also, just to be clear, on Monday, the day the  
02:53:46 9 trial started, there was a public announcement by AstraZeneca,  
02:53:51 10 not that the STRENGTH trial had failed but, that they were  
02:53:54 11 terminating study, and there's no publically available data as  
02:53:58 12 to the reasons why they terminated the study, what data they  
02:53:58 13 have.

02:54:02 14 So I don't even know that there's a basis for  
02:54:05 15 Mr. Sipes to assert that it failed because no one has seen any  
02:54:06 16 data, and there's been no public discussion that I'm aware of  
02:54:08 17 as to what the reasons were for terminating the trial.

02:54:12 18 One could infer certainly it wasn't going well,  
02:54:15 19 but I don't in any details or information about that, and  
02:54:18 20 either does Dr. Fisher.

02:54:19 21 THE COURT: I assume your question has nothing  
02:54:21 22 to do with the fact that the STRENGTH trial was terminated.

02:54:24 23 MR. SIPES: It goes to the point that it's how  
02:54:26 24 unpredictable this field is, that his opinion that JELIS  
02:54:31 25 rendered REDUCE-IT expected is undercut by the fact that, as

02:54:32 1 he acknowledged, JELIS would who have predicted a favorable  
02:54:39 2 outcome for STRENGTH, and STRENGTH did not get a favorable  
02:54:40 3 outcome.

02:54:40 4 MS. HUTTNER: First of all, that is a  
02:54:40 5 misrepresentation of the record. He did not say that.

02:54:43 6 He did not express the opinion that because of  
02:54:46 7 JELIS that he would expect the results of STRENGTH to be  
02:54:48 8 positive. He simply said it would be an interesting study to  
02:54:54 9 follow.

02:54:55 10 THE COURT: Let me pause for a moment. Who  
02:54:57 11 referenced the STRENGTH trial first in the deposition?

02:55:01 12 MR. SIPES: I believe I did.

02:55:01 13 THE COURT: All right. Let me read -- do you  
02:55:02 14 have -- let me read the transcript starting on page 156.

02:55:06 15 MS. HUTTNER: Do you need a copy, Your Honor?

02:55:10 16 THE COURT: Yes.

02:55:26 17 MS. HUTTNER: Your Honor, may I suggest that  
02:55:29 18 this would be a good time for a break? I believe Dr. Fisher  
02:55:32 19 could use a --

02:55:33 20 THE COURT: I know, I was planning on taking a  
02:55:35 21 break.

02:55:36 22 MS. HUTTNER: That way you could read the  
02:55:38 23 transcript.

02:55:40 24 THE COURT: Let's do that, I'll read the  
02:55:41 25 transcript. So I'm going to read page 155 through 157; is

02:55:46 1 that right?

02:55:49 2 MR. SIPES: To 158, Your Honor, I believe. Yes,  
02:55:52 3 it begins on 156 -- begins on 155 and goes through 158.

02:55:59 4 THE COURT: Thank you. Let's take a recess.

02:55:59 5 (A recess was taken.)

03:14:02 6 THE COURT: Please be seated.

03:14:02 7 All right. I have reviewed the portion of  
03:14:08 8 Dr. Fisher's deposition testimony starting on page 155,  
03:14:14 9 line 16, through page 158, line 20.

03:14:36 10 And I think that -- well, I'm overruling the  
03:14:40 11 objection. I agree with Mr. Sipes that given Dr. Fisher's  
03:14:45 12 deposition testimony, it is fair and adequate to ask him -- to  
03:14:55 13 question him about the portion of his deposition testimony  
03:14:58 14 where he testified about his vague familiarity with the  
03:15:03 15 STRENGTH trial, but his opinion -- his statement that there  
03:15:09 16 can be reasonable expectation -- well, he testified it would  
03:15:14 17 not surprise him if the STRENGTH trial achieved success.  
03:15:18 18 That's kind of the limitation of his testimony.

03:15:21 19 So, I'm overruling the objection. But I would  
03:15:25 20 have to say that I would give the testimony whatever weight it  
03:15:29 21 deserves. I know the parties are disputing this because had  
03:15:33 22 the STRENGTH trial not been terminated on Monday, perhaps the  
03:15:36 23 argument would have been very different.

03:15:39 24 MS. HUTTNER: Thank you, Your Honor.

03:15:40 25 MR. SIPES: Thank you, Your Honor.

03:15:40 1 BY MR. SIPES:

03:15:41 2 Q All right. Dr. Fisher, I suspect you know where I'm  
03:15:44 3 going to go next. So on this first -- in the JELIS trial, the  
03:15:49 4 patients were also consuming through diet some DHA, correct?

03:15:53 5 A Sure, as part of their natural consumption.

03:15:56 6 Q And so, in your view, the JELIS trial would be a good  
03:16:01 7 precedent that would make it a reasonable expectation that  
03:16:05 8 STRENGTH would be favorable, correct?

03:16:07 9 A You're reading that from the deposition? Is that --

03:16:10 10 Q Well, I'm asking you a question.

03:16:12 11 A Oh.

03:16:12 12 Q Would it help you if I were to play your deposition?

03:16:15 13 A No, no. I just read it, and sounded to be the same. So  
03:16:21 14 just please repeat the question. I didn't realize you were  
03:16:24 15 asking a question. I thought you were repeating part of my  
03:16:26 16 deposition.

03:16:27 17 Q Based on the fact that the patients in JELIS were  
03:16:29 18 consuming some DHA in their diet, JELIS would provide, in your  
03:16:34 19 opinion, a reasonable expectation that the STRENGTH trial  
03:16:37 20 would be favorable, correct?

03:16:42 21 A When I looked at what I wrote, I did ask you if they were  
03:16:45 22 on statins in the STRENGTH trial, and what I was thinking was  
03:16:50 23 that if you had an omega-3 effect without a rise in LDL, this  
03:17:00 24 would make it, at least from a lipoprotein point of view,  
03:17:09 25 somewhat equivalent.

03:17:11 1 And then I then said it was a reasonable expectation  
03:17:13 2 based on my taking into account that this is a  
03:17:15 3 statin-treated group as well. But, yes, that my final  
03:17:19 4 statement on that, there was a reasonable expectation.

03:17:21 5 MR. SIPES: And then, Mr. Brooks, if you'll pull  
03:17:23 6 up PX 1219 just to close the loop.

03:17:23 7 BY MR. SIPES:

03:17:28 8 Q PX 1219 is the press release from Monday, this Monday,  
03:17:34 9 reporting that AstraZeneca was terminating the STRENGTH trial  
03:17:40 10 due to its low likelihood of demonstrating a benefit to  
03:17:46 11 patients with mixed dyslipidemia who are at increased risk of  
03:17:51 12 cardiovascular disease, correct?

03:17:52 13 A Yes, that is what it says.

03:17:54 14 Q And so it appears the STRENGTH trial did not turn out  
03:17:59 15 favorably, correct?

03:18:00 16 A Yes, although we don't know the reason.

03:18:02 17 I suppose this happens sometimes. The event rate is  
03:18:06 18 very low, and you don't get to the prespecified minimum number  
03:18:11 19 of events, so it's declared futile.

03:18:14 20 I'm not saying, of course, that's the case here, but  
03:18:16 21 I have no idea why it has a low likelihood of demonstrating a  
03:18:22 22 benefit.

03:18:23 23 Q What we know is that the STRENGTH trial has not turned  
03:18:26 24 out favorably, correct?

03:18:27 25 A That is definitely correct, if they pulled the plug.

03:18:31 1 MR. SIPES: And I would move PX 1219 into  
03:18:35 2 evidence.

03:18:37 3 MS. HUTTNER: Your Honor, we would object. It's  
03:18:38 4 hearsay. I don't -- I don't see what probative value it has.  
03:18:44 5 It's a press release announcing that the study was terminated.

03:18:47 6 THE COURT: Well, is there any dispute the study  
03:18:50 7 was terminated?

03:18:50 8 MS. HUTTNER: It's on a public record, Your  
03:18:52 9 Honor. That's all we know is essentially what's in this press  
03:18:55 10 release. But, as Dr. Fisher pointed out, we don't know what  
03:19:03 11 the reason for the termination was.

03:19:05 12 THE COURT: Well, I'll admit the evidence for  
03:19:07 13 the sole purpose of supporting the statement that the STRENGTH  
03:19:10 14 trial was terminated without determining the reason for the  
03:19:13 15 termination.

03:19:13 16 MS. HUTTNER: Thank you, Your Honor.

03:19:14 17 THE COURT: So the evidence will be admitted for  
03:19:16 18 that limited purpose, which is the reason you're offering it  
03:19:19 19 in the first place, is that right, Mr. Sipes?

03:19:20 20 MR. SIPES: Correct. Correct.

03:19:20 21 (Plaintiff's Exhibit 1219 received in  
03:19:20 22 evidence.)

03:19:20 22 BY MR. SIPES:

03:19:29 23 Q So, Dr. Fisher, let's come back to the fact that the  
03:19:32 24 patients in JELIS were consuming omega-3s, including DHA, in  
03:19:38 25 their diet, correct?

03:19:38 1 A Yes.

03:19:38 2 Q In other words, that one issue with trials conducted in  
03:19:43 3 Japan is that the Japanese population consumes an unusually  
03:19:47 4 large amount of fish, correct?

03:19:50 5 A Well, for them it's not unusually large; compared to the  
03:19:55 6 U.S., yes.

03:19:55 7 MS. HUTTNER: I stand absolutely corrected.

03:19:56 8 THE COURT: All I know so far in this trial is I  
03:19:59 9 should continue to consume fish.

03:20:01 10 BY MR. SIPES:

03:20:02 11 Q A better question might be the Japanese population  
03:20:02 12 consumes a healthy amount of fish, correct?

03:20:04 13 A Yeah.

03:20:04 14 Q But now you had mentioned the MEGA trial as another  
03:20:09 15 cardiovascular trial that was conducted in Japan, correct?

03:20:13 16 A Yes.

03:20:13 17 Q That did not involve omega-3, correct?

03:20:16 18 A To my knowledge, no.

03:20:17 19 Q In fact, it involved pravastatin.

03:20:20 20 A Correct.

03:20:20 21 Q So this issue of the omega-3 baseline is not as relevant  
03:20:23 22 to the MEGA trial as it would be to understanding JELIS, for  
03:20:27 23 example?

03:20:27 24 A Yes.

03:20:28 25 Q And JELIS administered 1.8 grams of EPA, not 4 grams,

03:20:35 1 correct?

03:20:35 2 A Definitely.

03:20:36 3 Q And you don't cite today, in your testimony today, you  
03:20:40 4 did not cite any literature before 2008 that connects the  
03:20:44 5 blood levels of administering 4 grams per day in a western  
03:20:49 6 population, to 1.8 grams per day to a Japanese population,  
03:20:53 7 correct?

03:20:54 8 A Correct.

03:20:56 9 Q And, in fact, Amarin itself had information from its own  
03:21:06 10 trials about EPA blood levels from administering 4 grams per  
03:21:11 11 day, correct?

03:21:11 12 A Yes.

03:21:12 13 Q And that would include the MARINE trial and the ANCHOR  
03:21:15 14 trial, correct?

03:21:15 15 A Yes.

03:21:16 16 Q And so in designing REDUCE-IT, Amarin had information on  
03:21:22 17 blood levels of EPA that were not available in the literature.

03:21:26 18 A Correct.

03:21:27 19 Q And you -- at least when I deposed you, you were not  
03:21:40 20 willing to say whether the cardioprotective effects of, say, 2  
03:21:45 21 grams of EPA would be the same as 4 grams of EPA, correct?

03:21:49 22 A I take your word for it.

03:21:52 23 Q Well, let me ask you. Is it correct that you cannot  
03:21:58 24 opine on whether 2 grams of EPA would be as cardioprotective  
03:22:02 25 as 4 grams?

03:22:03 1 A It would depend, I think, on the blood levels achieved.  
03:22:07 2 And that's really what the cells see. So 2 grams a day  
03:22:11 3 provided to the cells, the equivalent, because of the  
03:22:14 4 background intake from natural sources, then I would say I  
03:22:19 5 would expect an effect that 2 grams versus 4 grams.

03:22:24 6 Q Okay. So that's the issue was trying to understand with  
03:22:27 7 supplementation how that's changing the blood levels in the  
03:22:30 8 patient's blood, correct?

03:22:32 9 A I think the blood levels are critical.

03:22:34 10 Q And certainly in a western population who is not  
03:22:37 11 consuming as much fish, even there you wouldn't be able to say  
03:22:41 12 whether 2 grams of EPA would be as cardioprotective 4 grams,  
03:22:47 13 correct?

03:22:48 14 A Until it was tested, that's correct.

03:22:50 15 Q Now, we have a considerable amount of evidence, do we  
03:22:53 16 not, that 1 gram of omega-3 fatty acids is not  
03:22:57 17 cardioprotective on top of a statin, correct?

03:23:00 18 A In the studies I discussed today, yes. But the design of  
03:23:06 19 those studies I would not say was optimal for testing an  
03:23:13 20 effect on cardiovascular risk. But, those studies were  
03:23:17 21 negative in their conclusions.

03:23:19 22 Q Okay. In terms of positive cardiovascular outcome trials  
03:23:24 23 on omega-3 fatty acids in patients on a statin, the only one  
03:23:29 24 that has met its primary endpoint has been REDUCE-IT, correct?

03:23:33 25 A Well, no, JELIS -- the primary endpoint was 19 percent

03:23:38 1 reduction at a significant P value.

03:23:42 2 Q And -- but all these other studies that we've been  
03:23:45 3 talking about, ASCEND and ORANGE --

03:23:47 4 A ORIGIN.

03:23:48 5 Q -- and ORIGIN, they failed to meet their primary  
03:23:51 6 endpoint, correct?

03:23:51 7 A Definitely.

03:23:52 8 Q Now, we spent some time, also, I think, talking about  
03:23:55 9 fibrates, correct?

03:23:56 10 A Yes.

03:23:58 11 MR. SIPES: And, Mr. Brooks, if you could pull  
03:24:06 12 up PX 162.

03:24:06 13 BY MR. SIPES:

03:24:11 14 Q This is the -- do you recognize PX 162 as the American  
03:24:17 15 Diabetes Association standard of care?

03:24:18 16 A Yes.

03:24:19 17 MR. SIPES: And if you will turn to, Mr. Brooks,  
03:24:24 18 to PX 162 at 11.

03:24:24 19 BY MR. SIPES:

03:24:30 20 Q The -- and this is from 2019, correct?

03:24:33 21 A Yes.

03:24:35 22 MR. SIPES: I believe this has already been  
03:24:35 23 admitted into evidence -- no?

03:24:42 24 Okay. I've been told I should move PX 162 into  
03:24:45 25 evidence.

03:24:45 1 THE COURT: Any objection?

03:24:47 2 MS. HUTTNER: No, Your Honor. I think this may  
03:24:48 3 be the same document as was admitted under defendants -- I'm  
03:24:52 4 sorry -- this was admitted under defendants' exhibit, but we  
03:24:54 5 have no objection.

03:24:55 6 THE WITNESS: It is.

03:24:58 7 THE COURT: Can I take your word for it?

03:24:59 8 MR. SIPES: Why don't we move it in --

03:25:01 9 THE COURT: I'm going to admit it into evidence.  
03:25:04 10 Don't worry, Mr. Sipes.

03:25:04 11 (Plaintiff's Exhibit 162 received in  
03:25:08 evidence.)

03:25:08 12 BY MR. SIPES:

03:25:08 13 Q If we turn to PX 162 at page 11, under Other Combination  
03:25:12 14 Therapy --

03:25:13 15 MR. SIPES: If you could blow that up.  
03:25:18 16 Recommendation 10.28?

03:25:18 17 BY MR. SIPES:

03:25:20 18 Q The ADA concludes in 2019,

03:25:22 19 "Combination therapy, statin fibrate, has not  
03:25:29 20 been shown to improve atherosclerotic cardiovascular  
03:25:32 21 disease outcomes, and is generally not recommended."

03:25:36 22 Do you see that? Did I read that correctly?

03:25:40 23 A The -- it's moving around.

03:25:42 24 Combination therapies, statin fibrate has not been  
03:25:46 25 shown to improve -- yes, I see that. So you read that

03:25:50 1 correctly.

03:25:51 2 Q Yes. So that's the position of the American Diabetes  
03:25:55 3 Association, correct?

03:25:55 4 A Yes.

03:25:55 5 MR. SIPES: And then if you'll go a little  
03:25:59 6 further down, in the middle column, statin and fibrate, and  
03:26:05 7 blow-up the first paragraph.

03:26:05 8 BY MR. SIPES:

03:26:06 9 Q Do you recall discussing earlier today the concern about  
03:26:10 10 combining a statin with fibrates? Do you recall discussing  
03:26:13 11 that, Dr. Fisher?

03:26:15 12 A Yes, I do.

03:26:15 13 Q And I think your testimony was that that's really a  
03:26:18 14 concern limited only to gemfibrozil, correct?

03:26:22 15 A No, I said there is a frequency with fenofibrates, but it  
03:26:26 16 was a lot lower than with gemfibrozil.

03:26:29 17 Q Okay. And, in fact, the American Diabetes Association  
03:26:32 18 recommends in 2019 that,

03:26:33 19 "Combination therapy, statin and fibrate, is  
03:26:36 20 associated with an increased risk for abnormal  
03:26:39 21 transaminase levels, myositis and rhabdomyolysis."

03:26:45 22 A Myolysis.

03:26:47 23 Q Myolysis.

03:26:49 24 "The risk of rhabdomyolysis is more common  
03:26:54 25 with higher doses of statins and renal insufficiency,

03:26:58 1 and appears to be higher when statins are combined  
03:27:01 2 with gemfibrozil (compared with fenofibrate).

03:27:07 3 Do you see that?

03:27:07 4 So that's consistent with the idea that there's  
03:27:09 5 a concern with all statins, but with all fibrates, but with  
03:27:12 6 gemfibrozil is particularly concerning, right?

03:27:15 7 A Gemfibrozil is particularly of concern. Statins actually  
03:27:20 8 have the same problem as monotherapy. And as I mentioned,  
03:27:24 9 that the last data that I saw of the rhabdomyolysis  
03:27:29 10 complication, which is the most serious of these, was about  
03:27:34 11 .12 percent, the combination of fenofibrate and a statin.

03:27:38 12 Q But rhabdomyolysis is muscle wasting, correct?

03:27:43 13 A It's the breakdown of muscle. You can call it just  
03:27:47 14 rhabdo. That's what we do in the field.

03:27:49 15 Q It's a very, very serious side effect, correct?

03:27:51 16 A Yes.

03:27:51 17 Q I can say that because my father was on Baycol, which had  
03:27:55 18 this as a particularly serious side effect, and it can be  
03:27:56 19 devastating to patients, correct?

03:27:57 20 A Yes, it can.

03:27:58 21 Q So even a 1 percent of risk of rhabdo is a very serious  
03:28:02 22 concern, correct?

03:28:03 23 A Yes. But, again, if you look at the data for statins  
03:28:07 24 alone, they have an above zero risk that is probably in that  
03:28:11 25 range.

03:28:11 1 Q And so combining it with a fibrate that might enhance the  
03:28:15 2 risk would be concerning, correct?

03:28:17 3 A Yes. That's why we monitor the patients on a frequent  
03:28:21 4 basis for their muscle enzymes, as well as their transaminase  
03:28:27 5 levels from their liver, as well as their renal function.

03:28:31 6 Q And one of the advantages of EPA and omega-3s, generally,  
03:28:36 7 is they have many fewer drug-drug interactions than, say,  
03:28:41 8 fibrates.

03:28:41 9 A That's a fair statement.

03:28:42 10 Q Now, if we go on with the ADA recommendations, the next  
03:28:46 11 paragraph says, in the ACCORD study -- do you see that?

03:28:49 12 A Uh-huh.

03:28:49 13 Q And you discussed the ACCORD study earlier today,  
03:28:55 14 correct? You recall discussing that?

03:28:56 15 A Yes.

03:28:56 16 Q And that was a study looking at cardiovascular outcomes  
03:29:00 17 in patients with Type 2 diabetes administered a combination of  
03:29:04 18 a statin and a fibrate, correct?

03:29:10 19 A Yes.

03:29:10 20 Q And in particular it was a fenofibrate as the fibrate,  
03:29:13 21 and simvastatin as the statin, correct?

03:29:15 22 A Yes.

03:29:16 23 Q And as the ADA guidance reports, it did not meet its  
03:29:21 24 primary endpoint, correct?

03:29:23 25 A Correct.

03:29:24 1 Q And they note that a prospective trial of a newer fibrate  
03:29:29 2 in this specific population of patients is ongoing, correct?

03:29:33 3 A Yes.

03:29:34 4 Q So people are still looking for ways to address  
03:29:37 5 cardiovascular risks in diabetes patients, even those on a  
03:29:37 6 statin, correct?

03:29:40 7 A Right. But you skipped over what I did introduce before  
03:29:44 8 about the subgroup analysis. They do acknowledge that there  
03:29:47 9 was a benefit in that group of greater than or equal  
03:29:52 10 204 milligrams per deciliter in HDL below 34.

03:29:57 11 Q But, nonetheless, their recommendation that's in section  
03:30:01 12 2.10.28 is combination therapy, statin fibrate has not been  
03:30:06 13 shown to improve atherosclerotic cardiovascular outcomes, and  
03:30:12 14 is generally not recommended, correct? That's the ADA  
03:30:13 15 guidance.

03:30:14 16 A By the ADA guideline, yes.

03:30:16 17 Q Okay. Now, the ADA has, in 2019, recommended EPA for  
03:30:21 18 residual cardiovascular risk, correct?

03:30:23 19 A They do recommend it, yes.

03:30:25 20 Q And that was a change in the ADA guidance from before,  
03:30:28 21 from 2018 and before, correct?

03:30:31 22 A That is correct.

03:30:31 23 Q So the change in the American Diabetes Association  
03:30:36 24 standards of medical care was as a result of the REDUCE-IT  
03:30:38 25 trial, correct?

03:30:39 1 A Yes. In terms of the EPA part, right.

03:30:45 2 Q And it was your testimony, it was your testimony at  
03:30:48 3 deposition, was it not, that currently fibrates are not used  
03:30:52 4 to reduce cardiovascular risks on top of a statin.

03:30:56 5 A Yes. That was based on the ACCORD and FIELD studies,  
03:31:03 6 yes.

03:31:04 7 Q Now, in March of 2008, it was still thought beneficial,  
03:31:11 8 from a cardiovascular perspective, to increase HDL  
03:31:17 9 cholesterol, correct?

03:31:18 10 A Yes.

03:31:18 11 Q And one mechanism that was looked at to try -- and the  
03:31:23 12 reason is -- so the pharmaceutical industry looked into drugs  
03:31:29 13 that would raise HDL as a way of addressing residual  
03:31:33 14 cardiovascular risk on top of a statin, correct?

03:31:36 15 A Yes.

03:31:36 16 Q And one area that they looked at was something called a  
03:31:39 17 CETP inhibitor, correct?

03:31:42 18 A Yes.

03:31:42 19 Q And I'm not going to ask you what CETP stands for because  
03:31:47 20 it doesn't matter. The point is these were new drugs that  
03:31:51 21 were being developed to raise HDL to address residual  
03:31:56 22 cardiovascular risk in patients on a statin, correct?

03:31:59 23 A Yes.

03:32:00 24 Q And the pharmaceutical industry devoted enormous time and  
03:32:05 25 money to developing CETP inhibitors in the latter half of the

03:32:11 1 2000s into 2010, correct?

03:32:12 2 A And beyond.

03:32:13 3 Q And beyond.

03:32:15 4 And, in your own words, the CEPT inhibitors were a  
03:32:21 5 colossal failure, correct?

03:32:22 6 A Yes, although I don't know if I was including the  
03:32:26 7 Anacetrapib. I'm not so good on dates, as we've discovered,  
03:32:32 8 of when these trials are reported.

03:32:34 9 But, the Merck study on Anacetrapib did have a  
03:32:40 10 statistically significant reduction in events, but they  
03:32:40 11 decided for a variety of reasons not to pursue the indication.

03:32:45 12 Q But your own description of the CETP inhibitors where a  
03:32:47 13 colossal failure, correct?

03:32:49 14 A Overall, yes.

03:32:50 15 Q And another thing that Merck tried to do was develop a  
03:32:55 16 niacin-based drug that was a combination of laropiprant and  
03:33:00 17 niacin, correct?

03:33:01 18 A Yeah. It's hard for me too. Laropiprant. And I would  
03:33:06 19 spell it, except I don't know how to spell it.

03:33:08 20 Q Okay. What is we call it Laro and niacin?

03:33:12 21 A Okay.

03:33:12 22 Q Or we can refer to it by its tradename Cordaptive,  
03:33:17 23 correct?

03:33:17 24 A Yes. That's better.

03:33:18 25 Q And Cordaptive was two drugs in one.

03:33:21 1 A Yes.

03:33:21 2 Q Which it's possible to take two active ingredients and  
03:33:27 3 put it in one drug product, correct?

03:33:29 4 A Correct.

03:33:29 5 Q And the niacin was intended to raise HDL.

03:33:32 6 A Yes.

03:33:33 7 Q And the other ingredient Iaro, or something like that,  
03:33:36 8 was really just intended to address the serious problem with  
03:33:39 9 flushing that comes about with niacin.

03:33:43 10 A Right. Tingling and flushing, yes.

03:33:46 11 Q And so even in 2010, when Merck was developing  
03:33:51 12 Cordaptive, raising HDL-C was still viewed as a possible way  
03:33:57 13 of addressing residual cardiovascular risk.

03:34:01 14 A Yes.

03:34:02 15 Q But Cordaptive failed as well, correct?

03:34:06 16 A It did. I think the problem, though, for that was there  
03:34:08 17 was safety issues related to the Laropiprant product, and so  
03:34:17 18 they pulled the plug on it and decided because other trials --  
03:34:22 19 there were involving niacin that were not effective, and so  
03:34:25 20 why do the additional safety studies if, ultimately, the  
03:34:29 21 niacin was not going to do something.

03:34:31 22 Q But -- and that was, really, 2010, that was the death  
03:34:36 23 knell of the forcibly raising HDL approach in the  
03:34:40 24 pharmaceutical industry, correct?

03:34:43 25 A Big pharma definitely lost interest and partly because

03:34:52 1 their understanding of HDL metabolism limited is limited. As  
03:34:56 2 Dr. Heinecke testified, he and I both have worked on HDL  
03:35:00 3 metabolism, that theirs a big distinction between functional  
03:35:04 4 HDL and dysfunctional.

03:35:06 5 And what has not been tested is a way to raise HDL  
03:35:12 6 that's functional, so that in terms of the hypothesis, is HDL  
03:35:17 7 raising good for you or not, has actually not been adequately  
03:35:22 8 tested.

03:35:22 9 But I would agree that the approaches that have been  
03:35:25 10 taken so far have not been successful.

03:35:29 11 Q Now, similarly, there was a belief at the time that  
03:35:32 12 increasing LDL particle size might be beneficial from a  
03:35:36 13 cardiovascular perspective because the LDL particles would  
03:35:40 14 then not as readily get into the lining of the arteries,  
03:35:43 15 correct?

03:35:43 16 A Some people -- I acknowledge some people felt that. I've  
03:35:50 17 never been a big fan of that work because I think, again, as  
03:35:53 18 Dr. Heinecke testified, going from 20 nanometers to  
03:35:58 19 22 nanometers is a very small difference.

03:36:03 20 Because it's not until you're getting up to these  
03:36:06 21 chylomicron size particles, or some of the particles in the --  
03:36:11 22 I mentioned before that in the severe hypertriglyceridemia  
03:36:13 23 patients, there is actually not a very high risk just from  
03:36:18 24 that because, as ATP III points out, the particles that are so  
03:36:22 25 big carrying so much triglyceride, can't penetrate the artery.

03:36:28 1 So they have to be fairly big before you penetrate  
03:36:31 2 an artery, and so -- again, I'm not saying people have thought  
03:36:34 3 about this bigger, fluffier LDL, versus smaller, denser, but  
03:36:40 4 the size difference of particles, other particles that size,  
03:36:44 5 freely get into the arterial wall.

03:36:47 6 Q It's turned out to be fairly difficult to predict what  
03:36:51 7 are the mechanisms that are truly going to reduce  
03:36:57 8 cardiovascular risk, correct?

03:36:58 9 A I agree with you.

03:36:59 10 Q You testified that you didn't believe there was a nexus  
03:37:22 11 between MARINE -- you know, the not raising LDL-C as an  
03:37:28 12 unexpected benefit in the claims because not every patient  
03:37:34 13 will enjoy that benefit, correct?

03:37:37 14 A Correct.

03:37:37 15 Q You'd agree, would you not, there is, invariably,  
03:37:43 16 variability in response to any drug.

03:37:45 17 A Yes.

03:37:46 18 Q There is no drug in which every patient responds exactly  
03:37:50 19 the same way.

03:37:51 20 A Maybe cyanide.

03:37:55 21 Q Depends on the dose.

03:38:00 22 Is it your testimony that to show nexus for a  
03:38:03 23 purported unexpected benefit, every patient study must show  
03:38:08 24 that benefit?

03:38:09 25 A No.

03:38:09 1 Q FDA views and evaluates the effects of drugs typically by  
03:38:16 2 looking at median patients, correct?

03:38:18 3 A Typically, yes.

03:38:19 4 Q And that tells you that at least half the patients are  
03:38:23 5 enjoying the reported benefit.

03:38:25 6 A Yes.

03:38:25 7 Q Okay. And the median patient in MARINE did not see a  
03:38:37 8 rise in LDL-C, correct?

03:38:39 9 A That's correct.

03:38:40 10 Q And the median patient actually saw a reduction in apo B,  
03:38:45 11 correct?

03:38:45 12 A Yes.

03:38:45 13 Q Now, you testified at -- that in many of your patients it  
03:39:15 14 takes them too long to get an appointment with a nutritionist,  
03:39:22 15 so you give them the drug right away; is that correct?

03:39:25 16 A Yes, concurrent with telling them -- informing them they  
03:39:31 17 need to improve their lifestyle and that we'll make  
03:39:34 18 arrangements for them to get the proper evaluation and  
03:39:39 19 recommendations.

03:39:39 20 Q Now, if you'll look in your reply -- in your report,  
03:39:44 21 DX 1574, at paragraph 51, which I think may be page 19 of the  
03:39:56 22 exhibit. But, I confess I'm guessing. Mr. Brooks will tell  
03:40:00 23 me.

03:40:00 24 Is that right, is it page 19?

03:40:02 25 MR. BROOKS: Eighteen.

03:40:02 1 BY MR. SIPES:

03:40:04 2 Q Eighteen. So 18, you opined in the last sentence in your  
03:40:08 3 report,

03:40:10 4 "Prescribing Vascepa without first placing a  
03:40:13 5 patient on an appropriate lipid-lowering diet, would,  
03:40:16 6 therefore, constitute an off-label use of Vascepa,"  
03:40:20 7 correct?

03:40:21 8 A Yes. Could you just point that -- I --

03:40:24 9 Q So paragraph 51, the very last --

03:40:28 10 MR. SIPES: If we could blow up the very last  
03:40:30 11 sentence.

03:40:30 12 BY MR. SIPES:

03:40:32 13 Q It's your opinion, is it not, that,

03:40:34 14 "Prescribing Vascepa without first placing a  
03:40:37 15 patient on an appropriate lipid-lowering diet would  
03:40:41 16 constitute an off-label use"?

03:40:43 17 A Correct. Sometimes you have to have patient safety come  
03:40:47 18 before a trivial off-label use.

03:40:51 19 If I'm telling a patient we need to put you on  
03:40:54 20 lifestyle modifications, but that cannot begin in the next few  
03:40:59 21 days, I just feel, just like Dr. Sheinberg, that I need to  
03:41:03 22 start getting those very high triglycerides down.

03:41:06 23 Q Right. And we'll come to that.

03:41:08 24 But in terms of the basis for the opinion you  
03:41:09 25 expressed in your report, you point to the Indications and

Usage section, the first sentence. You state,

"The Indications and Usage section expressly instructs that patients should be placed on an appropriate lipid-lowering diet and exercise regimen before" -- and you emphasize "before" -- "receiving Vascepa, and should continue this diet and exercise regimen with Vascepa."

That's what you wrote in your report, correct?

A That is correct.

Q And then you went on,

"The Dosage and Administration section repeats patients should engage in appropriate nutritional intake and physical activity before taking Vascepa which should continue during treatment of Vascepa."

That's also from your report, correct?

A Correct.

Q And then you go on,

"The patient counseling information likewise expressly instructs patients to start a diet low in saturated fat, cholesterol carbohydrates, and low in added sugars," correct?

A Correct.

Q But you're saying that sometimes patients -- it's so urgent that you don't take time to give them nutritional

03:42:09 1 counseling and exercise before you give them the drug,  
03:42:12 2 correct?

03:42:12 3 A Because it's impractical. If you look at this advice,  
03:42:17 4 it -- most patients can't interpret the simple nutrition label  
03:42:22 5 on a package of cookies. So to tell a patient, oh, I want you  
03:42:26 6 to eat less saturated fat, many patients don't even know what  
03:42:31 7 saturated fat is versus unsaturated.

03:42:34 8 As a practical method in a doctor's office, to do a  
03:42:39 9 comprehensive nutritional evaluation, and then on top of that  
03:42:42 10 an exercise evaluation, would take an hour or two. How many  
03:42:46 11 people in this room have actually sat in their doctor's office  
03:42:50 12 and had an hour of that person's time, unless it's psychiatry,  
03:42:52 13 of course. It's not practical. It's just not practical.

03:42:56 14 Q Now, one of the foundations of ATP III was what's called  
03:43:01 15 TLC, therapeutic lifestyle counseling, correct?

03:43:04 16 A Yes.

03:43:04 17 Q So ATP, in fact, emphasizes the importance of carrying  
03:43:08 18 out diet and lifestyle counseling.

03:43:10 19 A Yeah, I'm not saying it's not important.

03:43:12 20 MR. SIPES: Okay. Now, if we could pull up ATP  
03:43:14 21 III, PX 989 at 192. Well, first, we'll go to the first page  
03:43:23 22 to identify it, PX 191.

03:43:23 23 BY MR. SIPES:

03:43:27 24 Q This -- PX989 is ATP, is the ATP III report, correct?

03:43:32 25 A Correct.

03:43:32 1 Q You recognize that?

03:43:33 2 A Yes.

03:43:34 3 MR. SIPES: And this is already in evidence.

03:43:35 4 Everyone's nodding yes, so I'm going to say yes.

03:43:37 5 So now let's go to page 192, Mr. Brooks, and the  
03:43:44 6 very top paragraph.

03:43:44 7 BY MR. SIPES:

03:43:48 8 Q The very first sentence here on this page says,

03:43:51 9 "Because of the danger of acute pancreatitis,  
03:43:54 10 persons with severely elevated triglycerides greater  
03:43:57 11 then 2000 milligrams per deciliter should be treated  
03:44:01 12 as a medical urgency," correct?

03:44:02 13 A Yes.

03:44:03 14 Q And this is one of the reasons why trials in severe  
03:44:05 15 hypertriglyceridemia typically have inclusion criteria of 500  
03:44:09 16 to 2000, or 500 to 1500, is to have the patients who aren't in  
03:44:13 17 a situation of medical urgency, correct?

03:44:16 18 A Yes, but we also heard that triglycerides vary  
03:44:21 19 considerably in a day, from day-to-day within a day, and it  
03:44:25 20 depends if you're a betting person.

03:44:28 21 Again, we're in Reno, but I'm not going to be  
03:44:32 22 somebody calculating if you have a 10 percent chance, a  
03:44:37 23 50 percent chance, a 100 percent chance of pancreatitis, I'm  
03:44:40 24 not going to take that bet on the patient. I'm going to be  
03:44:43 25 conservative and say, ah, above 500, if it says the risk is

03:44:48 1 for acute pancreatitis is a clinical consideration, then I'm  
03:44:53 2 going to treat as soon as I can.

03:45:02 3 Q And so when you treat patients with severe  
03:45:06 4 hypertriglyceridemia, you are concerned that their  
03:45:09 5 triglycerides may spike, so you put them on the drug.

03:45:14 6 Am I understanding you correctly?

03:45:16 7 A Yes.

03:45:16 8 Q And, now, let us understand that.

03:45:18 9 So treating severe hypertriglyceridemia means  
03:45:21 10 keeping the patient's triglycerides are below 500 --

03:45:24 11 MS. HUTTNER: Your Honor, objection. This is  
03:45:26 12 clearly going into the infringement issues that were discussed  
03:45:29 13 with Dr. Heinecke -- I'm sorry -- with Dr. Sheinberg and  
03:45:34 14 Dr. Budoff.

03:45:34 15 He's about to ask him about whether it's a  
03:45:37 16 chronic disease, not a chronic disease. I mean, this is not  
03:45:41 17 anything that Dr. Fisher opined about, nor does it pertain to  
03:45:44 18 the issues that Dr. Fisher addressed. This is, clearly, about  
03:45:47 19 infringement.

03:45:48 20 MR. SIPES: Your Honor, let me respond to that.

03:45:50 21 They went into with him the idea of how he  
03:45:53 22 treats these patients because of this risk in going up. I'm  
03:45:55 23 entitled to inquire into the same subject matter.

03:45:59 24 MS. HUTTNER: With respect to whether it's  
03:46:01 25 treating for pancreatitis. But this is going into the

question of whether or not severe hypertriglyceridemia is a chronic illness or an acute illness, which was -- as Your Honor knows, that was the issue that Your Honor raised in the summary judgment opinion with respect to infringement. This is clearly an infringement issue.

MR. SIPES: Your Honor, if she wants to object to a question about chronic, she can object when that comes. But this idea of preempting a whole line of questioning that is directly on the same topic that they've just covered is improper.

MS. HUTTNER: Well, I think that your question --

THE COURT: Hang on, Ms. Huttner.

I agree with Mr. Sipes. He hasn't asked any question about chronic versus acute illness. Dr. Fisher did allude to other testimony about the variation in TG throughout the day. That's a different issue all together.

But Dr. Fisher was asked on direct examination about his practice and his -- how he prescribes for patients with high -- with severe TH -- severe HTG. I'm not even going to try to pronounce the actual words.

MS. HUTTNER: We won't think less of you, Your Honor.

THE COURT: So I think that this is a fair area of examination. If Mr. Sipes goes into details about chronic

03:47:15 1 versus acute, then you can object.

03:47:17 2 MS. HUTTNER: Fair enough.

03:47:17 3 BY MR. SIPES:

03:47:19 4 Q So, anyway, in treating severe hypertriglyceridemia, the  
03:47:24 5 goal is to keep the patients below 500 milligrams per  
03:47:28 6 deciliter, correct?

03:47:29 7 A That is correct.

03:47:30 8 Q Yes. And you've testified, not only do you have to put  
03:47:33 9 them on quickly to get them under 500, but the patients need  
03:47:37 10 to stay on their TG-lowering medication in order to keep their  
03:47:41 11 triglycerides below 500 milligrams per deciliter.

03:47:44 12 A Many do, but not all, because we've heard, also, about  
03:47:47 13 drugs that can cause this -- medical conditions like  
03:47:54 14 hyperthyroidism, hormones, et cetera. But, many. I would say  
03:47:58 15 many, but not all.

03:47:59 16 Q In fact, it was your testimony that, in general, when get  
03:48:03 17 the patient below 500, you will keep them on -- the majority  
03:48:06 18 of patients will need to stay on because you just don't know  
03:48:06 19 if you take them off whether or not -- I think your term was,  
03:48:09 20 bingo, it will go back up again, correct?

03:48:11 21 A It definitely could go back up.

03:48:14 22 Q Yes. So it's your testimony that frequently a patient is  
03:48:17 23 kept on triglyceride-lowering, essentially, as a prophylactic  
03:48:23 24 to make sure that the triglycerides are maintained below 500,  
03:48:27 25 correct?

03:48:32 1 A Yes.

03:48:32 2 Q And, in your experience, even for a highly motivated  
03:48:42 3 patient -- excuse me -- even for a motivated patient, it takes  
03:48:46 4 at least six months for that patient to lose enough weight to  
03:48:51 5 be ready to get off their medication, right?

03:48:54 6 A Yes. My experience, it will take months, and six months  
03:48:59 7 is, you know, plus or minus.

03:49:02 8 Q And many patients, of course, are not motivated patients,  
03:49:05 9 who are able to lose sufficient weight in six months, correct?

03:49:10 10 A That is for sure true.

03:49:15 11 Q There is no consensus among those skilled in the art  
03:49:23 12 about the mechanisms by which Vascepa produces an alleged  
03:49:29 13 cardiac benefit in certain patients, correct?

03:49:31 14 A That is correct.

03:49:32 15 Q And those mechanisms simply -- were similarly not well  
03:49:35 16 understood in 2008, correct?

03:49:37 17 A Well, mechanisms in preclinical models certainly were  
03:49:44 18 established by 2008 that would be plausible explanations, but  
03:49:48 19 as Director of Translational Research, as we heard, the  
03:49:52 20 ability to do direct investigations in people to confirm that  
03:49:59 21 a potential mechanism is actually operating is very difficult.

03:50:03 22 Q Now, you, in your testimony today, went through a number  
03:50:08 23 of different trials of fibrates and other agents,  
03:50:15 24 triglyceride-lowering agents, that were undertaken to address  
03:50:20 25 cardiovasculars, correct?

03:50:22 1 A Yes.

03:50:23 2 Q There were also a number of trials that went on, even  
03:50:26 3 that were underway even as of March 2008, of different  
03:50:30 4 mixtures of omega-3 fatty acids, correct?

03:50:33 5 A I'm not recalling which ones.

03:50:35 6 Q Do you recall the Alpha Omega trial?

03:50:38 7 A I do not.

03:50:40 8 MR. SIPES: Mr. Brooks, if you could pull up  
03:50:42 9 PX492, blow up the top.

03:50:42 10 BY MR. SIPES:

03:50:47 11 Q So, Dr. Fisher, this is a publication called "n-3 Fatty  
03:50:53 12 Acids and Cardiovascular Events After Myocardial Infarction."  
03:50:58 13 The first author is Daan Kromhout, and I'm sure I've mangled  
03:51:05 14 the pronunciation of his name, for the Alpha Omega trial  
03:51:06 15 group, and it was published in the *New England Journal of*  
03:51:10 16 *Medicine*.

03:51:11 17 Do you see that?

03:51:12 18 A Yes.

03:51:12 19 MR. SIPES: And I would move PX 492 into  
03:51:15 20 evidence.

03:51:15 21 MS. HUTTNER: Your Honor, it hasn't been  
03:51:17 22 established whether Dr. Fisher has reviewed this article, and  
03:51:21 23 I don't know that there's a foundation at this point.

03:51:23 24 THE COURT: I think that's a fair point.  
03:51:25 25 Dr. Fisher said he's familiar with the article. Perhaps you

03:51:28 1 could lay some additional foundation, Mr. Sipes.

03:51:31 2 MR. SIPES: I would be happy to do so.

03:51:32 3 BY MR. SIPES:

03:51:33 4 Q So first, it's published in the *New England Journal of*  
03:51:35 5 *Medicine*, correct?

03:51:35 6 A Yes, but I do not recall it.

03:51:37 7 Q That is among the most prestigious medical journals,  
03:51:42 8 correct?

03:51:42 9 A Without a doubt, yes.

03:51:49 10 MR. SIPES: And let me just see if I can -- go  
03:51:58 11 to the -- just the background -- no, I'm sorry, it's on  
03:52:02 12 page 0002, the study design method. Thank you. The study  
03:52:09 13 design, the very top.

03:52:09 14 BY MR. SIPES:

03:52:09 15 Q Okay.

03:52:11 16 "The Alpha Omega trial was a multicentered,  
03:52:15 17 double-blind, placebo-controlled trial, with 2-by-2  
03:52:18 18 factorial design which has been described in detail  
03:52:21 19 previously."

03:52:22 20 Do you see that?

03:52:23 21 A Yes.

03:52:23 22 Q And then if we go down, in the right-hand column -- let  
03:52:28 23 me get this out -- in the second paragraph, there is --  
03:52:42 24 "Patients were enrolled from 2002 through December 2006."

03:52:46 25 Do you see that?

03:52:47 1 A Yes.

03:52:47 2 Q Here we go. I'm sorry.

03:52:54 3 And then if we go further down, after this period --  
03:53:00 4 why don't you -- keep reading down.

03:53:04 5 "The patients received one of four trial  
03:53:07 6 margarines, a margarine with no additional n-3 fatty  
03:53:13 7 acids (placebo margarine), or a margarine with  
03:53:14 8 approximately 400 milligrams of EPA/DHA per day, 2  
03:53:19 9 grams of ALA per day, or a combination of EPA/DHA and  
03:53:19 10 ALA."

03:53:24 11 Do you see that?

03:53:30 12 A Yes, I do.

03:53:32 13 Q Does this bring you back to the fact that there was a  
03:53:32 14 trial going on about different mixtures of EPA and DHA?

03:53:32 15 A Right, at relatively low levels.

03:53:34 16 MR. SIPES: Your Honor, now I would move PX 492  
03:53:38 17 into evidence.

03:53:39 18 MS. HUTTNER: Your Honor, I don't think he has,  
03:53:41 19 as yet, established that Dr. Fisher is familiar with this  
03:53:45 20 article or the study that's discussed in this article. He's  
03:53:47 21 simply pointed him to a description of the study in the  
03:53:47 22 article.

03:53:50 23 THE COURT: I agree. Dr. Fisher hasn't  
03:53:52 24 testified that he has reviewed the article, is thoroughly  
03:53:57 25 familiar with it. Basically, you asked him what the article

03:54:00 1 says, and he agrees that's what it says.

03:54:00 2 BY MR. SIPES:

03:54:02 3 Q Do you recall being familiar with the Alpha Omega  
03:54:05 4 trial --

03:54:05 5 A No.

03:54:06 6 Q -- Dr. Fisher?

03:54:07 7 Okay. So you were not following -- well, let me ask  
03:54:10 8 you, were you following omega-3 trials during the 2000-2010  
03:54:15 9 period?

03:54:15 10 A I was more focused on the basic science of how the  
03:54:21 11 omega-3 fatty acids were working in the liver.

03:54:25 12 Q And let me ask you, are you familiar with --

03:54:32 13 MR. SIPES: Well, Mr. Brooks, if you could pull  
03:54:33 14 up PX 956.

03:54:33 15 BY MR. SIPES:

03:54:42 16 Q And the title here is "Cardiovascular Effects of B  
03:54:45 17 Vitamins and/or n-3 Fatty Acids, The SU.FOL.OM3 Trial."

03:54:53 18 Do you see that?

03:54:53 19 A Yes, I do.

03:54:53 20 Q And do you recall the SU.FOL.OM3 trial?

03:54:57 21 A I do not.

03:54:58 22 MR. SIPES: Okay. And just to see if I can jog  
03:55:06 23 your memory, if we go to the second page, Mr. Brooks, blow up  
03:55:17 24 under Population, the first paragraph under Population.

03:55:17 25

03:55:17 1 BY MR. SIPES:

03:55:24 2 Q It says, the second sentence,  
03:55:26 3 "Briefly, the SU.FOL.OM3 trial was a  
03:55:29 4 double-blind, randomized, placebo-controlled  
03:55:32 5 secondary prevention trial designed to test the  
03:55:34 6 efficacy of folate supplementation in combination  
03:55:38 7 with vitamin B6 and B12 and/or n-3 PUFA (600  
03:55:45 8 milligrams of icosapentaenoic acid and  
03:55:49 9 docosahexaenoic acid at a ratio of 2-to-1) on fatal  
03:55:50 10 and non-fatal ischemic cardiovascular disease."

03:55:53 11 Do you see that?

03:55:54 12 A I do see that.

03:55:55 13 Q And note the reference to icosapentaenoic acid and  
03:55:49 14 docosahexaenoic acid is EPA and DHA.

03:56:04 15 A Correct.

03:56:04 16 Q And specifically there in a ratio of 2-to-1, correct?

03:56:08 17 A That's what it says.

03:56:08 18 Q So this is the SU.FOL.OM3 trial, another cardiovascular  
03:56:14 19 outcome trial of an omega-3, correct?

03:56:17 20 A It is. I've never seen it before, but clearly it is.

03:56:22 21 Q So you are not familiar with that trial either, correct?

03:56:25 22 A No.

03:56:25 23 Q Okay.

03:56:26 24 A Which is good because now I have fewer questions to  
03:56:31 25 answer.

03:56:31 1 Q Are you familiar with the Risk and Prevention Study  
03:56:37 2 Collaborative Group?

03:56:39 3 A I have a vague recollection of hearing that group --  
03:56:44 4 hearing of -- of hearing about that group.

03:56:47 5 MR. SIPES: Okay. Let me see -- if you're  
03:56:49 6 familiar with it, why don't we pull up PX 949. Look at the --  
03:56:56 7 if you can blow up the top.

03:56:57 8 BY MR. SIPES:

03:56:57 9 Q So this is a -- PX 949 is another article from the *New*  
03:57:03 10 *England Journal of Medicine* entitled "n-3 Fatty Acids in  
03:57:05 11 Patients with Multiple Cardiovascular Risk Factors."

03:57:09 12 Do you see that?

03:57:10 13 A I do.

03:57:10 14 Q And it's from the Risk and Prevention Study Collaborative  
03:57:15 15 Group.

03:57:15 16 A Yes.

03:57:15 17 Q And under Results, they note,

03:57:19 18 "Of the 12,513 patients enrolled, 6,244 were  
03:57:25 19 randomly assigned to n-3 fatty acids, and 6,269 to  
03:57:30 20 placebo."

03:57:30 21 Do you see that?

03:57:31 22 A I do.

03:57:31 23 Q And the term n-3 fatty acids I think we've heard before,  
03:57:35 24 that's another term for omega-3 fatty acids, correct?

03:57:38 25 A Yes.

03:57:38 1 Q And if we go to page 02 to 03, it reads,

03:57:49 2 "Study procedures. Study patients were  
03:57:52 3 randomly assigned to receive one capsule daily  
03:57:55 4 containing 1 gram of n-3 fatty acids (polyunsaturated  
03:57:59 5 fatty acid ethyl esters) with EPA and DHA content not  
03:58:07 6 less than 85 percent in a ratio that could range from  
03:58:11 7 0.9 to 1 to 1.5 to 1 or a placebo (olive oil)."

03:58:18 8 Do you see that?

03:58:19 9 A I do.

03:58:19 10 Q So the Risk and Prevention study was another large  
03:58:25 11 cardiovascular trial of omega-3 fatty acid mixtures, correct?

03:58:26 12 A Yes.

03:58:26 13 Q And are you familiar with that one?

03:58:28 14 A I haven't seen it in years, but I remember when it --  
03:58:32 15 when it did come out. But I -- I'm definitely not familiar  
03:58:36 16 with the details. I just remember the bottom line.

03:58:39 17 Q Okay. And this was a study that was conducted --

03:58:46 18 MR. SIPES: Well, if you'll turn, Mr. Brooks, to  
03:58:52 19 PX 949 at 0004. And the trial participants under the  
03:59:01 20 left-hand column Results.

03:59:02 21 BY MR. SIPES:

03:59:02 22 Q So the trial -- there was enrolled between February 2004  
03:59:08 23 and March 2007 with a total 12,513 patients, correct?

03:59:14 24 A Yes.

03:59:14 25 Q And then the results were published in this article in

03:59:17 1 2013, correct?

03:59:18 2 A Yes.

03:59:19 3 Q But you don't -- you don't recall the Risk and Preventive  
03:59:25 4 study results in any detail, I take it, correct?

03:59:27 5 A Just that it was a negative study.

03:59:30 6 Q It -- as we go to the first page under Conclusions, the  
03:59:35 7 conclusion was,

03:59:36 8 "In a large general practice cohort of  
03:59:38 9 patients with multiple cardiovascular risk factors,  
03:59:41 10 daily treatment with n-3 fatty acids did not reduce  
03:59:45 11 cardiovascular mortality and morbidity," correct?

03:59:48 12 A Right, that's the part I remember.

03:59:50 13 Q It's fair to say that a variety of trials on a variety of  
03:59:54 14 mixtures of EPA and DHA were being conducted in the period up  
03:59:59 15 through March of 2008, correct?

04:00:00 16 A Yes.

04:00:01 17 MS. HUTTNER: Your Honor, I would object to be  
04:00:03 18 that. There was no data established on any of the studies  
04:00:06 19 that Mr. Sipes asked about. I believe that many of them were  
04:00:11 20 conducted after 2008. So I don't think it's a fair question  
04:00:16 21 that was just asked.

04:00:18 22 THE COURT: Well, the question --

04:00:21 23 MS. HUTTNER: He showed him a series of -- asked  
04:00:23 24 him a series of questions about clinical studies which were  
04:00:26 25 not tied to when those studies were published, and then

1 followed that with a question that says so there were a lot of  
2 trials prior to 2008, you know, creating the inference that  
3 the studies he was asking about were conducted before 2008  
4 which I do not believe was the case.

5 THE COURT. Mr. Sipes?

6 MR. SIPES: Actually, that is the case. We just  
7 went through one that was enrolled between 2004 and 2007. We  
8 can go through the date of the others.

9 But, more to the point, I asked him the general  
10 question which is true, there were a number of trials going on  
11 with different mixtures of EPA and DHA throughout this period  
12 up through March of 2008, and he answered truthfully and  
13 correctly.

14 MS. HUTTNER: Yeah, as long as it's clear that  
15 while the studies may have been conducted during those  
16 periods, the results of those studies were not necessarily  
17 published prior to 2008, and I believe in several cases, at  
18 least, that it was published after that date.

19 MR. SIPES: I will make clear that in each of  
20 these studies the studies themselves were being conducted of  
21 different mixtures of EPA and DHA throughout the period  
22 through March of 2008, and the results were published later.

23 THE COURT: Well, regardless, those studies have  
24 not been admitted, but I think the question, it's fair, and I  
25 overrule the objection, because the question goes beyond what

04:01:38 1 was in the various exhibits that Mr. Sipes was inquiring of  
04:01:43 2 Dr. Fisher.

04:01:43 3 BY MR. SIPES:

04:01:47 4 Q Dr. Fisher, do you recall testifying about an article,  
04:01:50 5 the Surette article in your direct examination?

04:01:53 6 A I do.

04:01:54 7 MR. SIPES: And if we could pull up DX 2144.

04:01:54 8 BY MR. SIPES:

04:01:58 9 Q This is the Surette article, correct?

04:02:01 10 A Yes.

04:02:01 11 Q And you talked about it during your direct. It is a  
04:02:06 12 review article, correct?

04:02:08 13 A That is correct.

04:02:08 14 Q In fact, the word review appears quite prominently in the  
04:02:12 15 upper right-hand corner of paper, correct?

04:02:15 16 A It does.

04:02:16 17 Q And it was published in January 15th, 2008, correct?

04:02:19 18 A Yes.

04:02:20 19 Q So this is review article of the science between dietary  
04:02:25 20 omega-3 fatty acids published in January of 2008, correct?

04:02:27 21 A Yes.

04:02:27 22 Q And then you reviewed it for -- mentioning of all these  
04:02:32 23 different possible biological actions of omega-3 fatty acids,  
04:02:36 24 correct?

04:02:36 25 A Yes.

04:02:37 1 Q The article describes a number of different actions of  
04:02:41 2 omega-3 fatty acids, correct?

04:02:42 3 A It does.

04:02:43 4 Q It never attributes any particular biological activity to  
04:02:47 5 EPA rather than DHA, correct?

04:02:50 6 A That is correct.

04:02:51 7 Q It speaks just generally about omega-3 fatty acids,  
04:02:54 8 correct?

04:02:54 9 A Yes.

04:02:56 10 MR. SIPES: Let me -- Your Honor, if I could  
04:02:57 11 confer briefly with my colleagues.

04:03:24 12 (Discussion held off the record.)

04:03:24 13 BY MR. SIPES:

04:03:24 14 Q Dr. Fisher, you testified that, not just you, but a  
04:03:35 15 number of your colleagues as well, in your experience, even  
04:03:40 16 when Vascepa was approved, tended to stick with Lovaza,  
04:03:44 17 correct?

04:03:45 18 A Yes.

04:03:45 19 Q And at deposition you testified that even if Vascepa had  
04:03:57 20 been available in March of 2008, a person of ordinary skill in  
04:04:03 21 the art would have stuck with Lovaza, correct?

04:04:06 22 A I assume you're reporting what I said accurately. But  
04:04:10 23 maybe -- I -- I can hear the exact words or see them on the  
04:04:15 24 deposition?

04:04:16 25 MR. SIPES: Sure. Mr. Brooks, if we could play

04:04:19 1 263, 3 to 20.

04:04:21 2 (Deposition video recording played.)

04:04:21 3 BY MR. SIPES:

04:05:23 4 Q And, in fact, I asked you as well, when Lovaza was  
04:05:28 5 approved whether or not -- when Lovaza was approved people  
04:05:33 6 were saying it's a mistake to have DHA in Lovaza.

04:05:37 7 And you said you didn't recall you or your  
04:05:40 8 colleagues or people at the National Lipid Association  
04:05:43 9 meetings going, "My God, they got to get this DHA out of  
04:05:47 10 there."

04:05:47 11 Do you recall that?

04:05:48 12 A Yes.

04:05:48 13 Q And that was true, correct?

04:05:51 14 A Correct.

04:05:52 15 Q In fact, your testimony was there was in the  
04:05:55 16 literature -- actually, it went back and forth. There were  
04:05:58 17 publications that actually say that DHA might lower LDL more,  
04:06:03 18 correct?

04:06:03 19 A That's correct.

04:06:04 20 Q And so you said the issue had been raised before 2004,  
04:06:09 21 that EPA and DHA might have differential effects, but was no  
04:06:09 22 conclusions drawn about which would be superior therapy based  
04:06:13 23 on that.

04:06:14 24 That was your testimony, correct?

04:06:15 25 A I would say there was still controversy at that time.

04:06:18 1 Q And so this is the basis for your testimony earlier today  
04:06:22 2 that people weren't switching immediately from Lovaza to  
04:06:27 3 Vascepa, correct?

04:06:28 4 A Yes.

04:06:29 5 Q Now we know a lot more about the differential effects of  
04:06:35 6 Lovaza and Vascepa, correct?

04:06:36 7 A Yes.

04:06:37 8 Q Now would you prefer Vascepa rather than Lovaza?

04:06:43 9 A Depends on the application. I think in the high  
04:06:49 10 triglyceride group with the evidence-based medicine that  
04:06:52 11 there's a reduction in cardiovascular risk, I would prefer  
04:06:56 12 Vascepa.

04:06:57 13 I think for the situation of the severe  
04:07:01 14 hypertriglyceridemic patient, particularly in the diabetic  
04:07:05 15 population, that's already on a statin, I would make the  
04:07:10 16 decision on other factors, for example, the availability of a  
04:07:14 17 generic.

04:07:17 18 MR. SIPES: Your Honor, I have no further  
04:07:19 19 questions at this time.

04:07:21 20 THE COURT: Dr. Fisher, how are you doing? Are  
04:07:34 21 you all right to continue, or do you want to request a break?

04:07:39 22 It depends on how long Ms. Huttner plans to  
04:07:42 23 redirect, is that right?

04:07:44 24 THE WITNESS: I have been drinking a lot of  
04:07:46 25 water here.

04:07:47 1 MS. HUTTNER: We can take a break, Your Honor.

04:07:49 2 THE COURT: Why don't we take a break. I  
04:07:51 3 realize you're also on different time zones. Let's take a  
04:07:54 4 brief recess.

04:07:54 5 MS. HUTTNER: And I did not believe I will be  
04:07:56 6 very long on redirect, but we can complete it after.

04:08:00 7 THE WITNESS: I just need five minutes.

04:19:20 8 (A recess was taken.)

04:19:20 9 THE COURT: Please be seated.

04:19:20 10 REDIRECT EXAMINATION

04:19:20 11 BY MS. HUTTNER:

04:19:29 12 Q Dr. Fisher, I just want to clarify a few points that came  
04:19:34 13 up during cross-examination.

04:19:35 14 First of all, I want to focus on your role in seeing  
04:19:41 15 patients in the time frame after you came back from Oxford  
04:19:46 16 which I think you said was in 2010; is that right?

04:19:49 17 A 2011.

04:19:50 18 Q 2011. After you came back from Oxford, did you continue  
04:19:52 19 to see patients in the clinics?

04:19:54 20 A Not in the outpatient clinic, just inpatient  
04:19:54 21 consultations.

04:19:59 22 Q Okay. And you described that in your direct testimony?

04:20:01 23 A I did.

04:20:01 24 Q This is the situation where you accompany fellows to  
04:20:06 25 teach them how to treat patients, is that what you're

04:20:09 1 preferring to?

04:20:09 2 A In preventive cardiology, yes.

04:20:11 3 Q Okay. And in that role, I think you testified to the  
04:20:14 4 fact that you evaluate the patients and you have to sign-off  
04:20:18 5 on the charts of those patients as far as treatment  
04:20:21 6 recommendations?

04:20:21 7 A Yes, I'm the attending physician of record.

04:20:23 8 Q Okay. And since you graduated medical school in 1975,  
04:20:28 9 has there been any period when you haven't seen patients aside  
04:20:31 10 from the time you were at Oxford?

04:20:34 11 A No, it's been continuous since then.

04:20:37 12 Q And just to close the loop on this, after Vascepa was  
04:20:43 13 approved, did you or others under your supervision prescribe  
04:20:48 14 or recommend Vascepa for -- to patients for any reason?

04:20:52 15 A Yes. Short answer, yes.

04:20:54 16 Q And in a related vein, there were a number of questions,  
04:20:59 17 and I just want to clarify, and I think you did this in your  
04:21:03 18 answer to Mr. Sipes' question, but just to clarify, I want to  
04:21:07 19 distinguish between patients with high triglycerides on the  
04:21:11 20 one hand, in other words, below 500, and patients with very  
04:21:14 21 high triglycerides, above 500.

04:21:17 22 With respect to very high patients -- I'm sorry,  
04:21:21 23 with respect -- it's late in the day, Your Honor. I'm going  
04:21:24 24 start again.

04:21:25 25 With respect to patients with severe

04:21:27 1 hypertriglyceridemia, meaning triglycerides in excess of  
04:21:31 2 500 milligrams per deciliter, did -- in that group, did you  
04:21:38 3 change your prescribing practices when Vascepa was approved?

04:21:41 4 A No.

04:21:44 5 Q And I think you said during your direct testimony that  
04:21:47 6 the goal with patients -- the medical goal with patients in  
04:21:51 7 this bucket of very high triglycerides is to reduce  
04:21:54 8 triglycerides to avoid pancreatitis; is that correct?

04:21:57 9 A Yes.

04:21:58 10 Q And in terms of the ability to lower triglycerides in  
04:22:02 11 patients with very high triglycerides, is there any advantage  
04:22:05 12 to Vascepa over fibrates or Lovaza?

04:22:09 13 A No.

04:22:09 14 Q They all lower triglycerides equally well?

04:22:12 15 A By about the same percentage.

04:22:14 16 Q And I think you testified that there -- fibrates were the  
04:22:17 17 number one drug that you prescribed to that group to lower  
04:22:20 18 triglycerides?

04:22:21 19 A Yes.

04:22:21 20 Q And that after Lovaza was approved, or at least after  
04:22:26 21 Lovaza went generic, that in terms of the fish oil products,  
04:22:31 22 there was a slight -- there was preference for Lovaza because  
04:22:33 23 of the cost to the patient?

04:22:35 24 A Yes.

04:22:36 25 Q All right. Now, and did that change when the REDUCE-IT

04:22:40 1 results were announced?

04:22:42 2 A Well, I haven't --

04:22:43 3 Q In the group of very high triglyceride patients.

04:22:45 4 A I don't have direct experience in that group, but -- so I  
04:22:51 5 can't really -- I can't really say -- that situation did not  
04:22:55 6 come up in my consultations that I've done.

04:22:59 7 Q Okay. So you're saying that after Vascepa came on the  
04:23:02 8 market in 2013, to your -- you don't recall having treated a  
04:23:06 9 patient with very high triglycerides?

04:23:08 10 A That is correct.

04:23:09 11 Q Okay. Now, you were asked some questions about the  
04:23:18 12 interactions between statin drugs and fibrates as it relates  
04:23:25 13 to rhabdomyolysis, correct?

04:23:28 14 A Rhabdomyolysis.

04:23:30 15 Q I thought I got it right.

04:23:30 16 A Just call it rhabdo.

04:23:32 17 Q Rhabdo. Okay. I was trying to go for the big get there,  
04:23:34 18 but I failed.

04:23:35 19 And I think, again, that you testified during your  
04:23:39 20 direct examination, but I just want to clarify, the problem  
04:23:43 21 with fibrate drugs, as distinct from fenofibrate drugs, but  
04:23:48 22 the problem with fibrate drugs, and, in particular,  
04:23:51 23 gemfibrozil, was that it interacted -- it could interact with  
04:23:55 24 the statin, particularly the statin drug that you mentioned  
04:23:57 25 that was withdrawn from the market to cause this disease

04:24:03 1 rhabdo, right?

04:24:04 2 A Yes.

04:24:06 3 Q And am I correct in understanding that that was because  
04:24:10 4 Gemfibrozil and statin drugs have the same mechanism of  
04:24:14 5 action?

04:24:14 6 A No. They are metabolized in the liver by an enzyme  
04:24:22 7 system common to both. So the Gemfibrozil would compete for  
04:24:28 8 the enzyme, and the statin metabolites that were produced were  
04:24:36 9 thought to be more toxic.

04:24:38 10 Q And is that issue that you've just described, is that a  
04:24:42 11 problem with Tricor, which is a fenofibrate drug?

04:24:45 12 A No. They're metabolized by a different system.

04:24:49 13 Q And I think you said this in response to one of  
04:24:52 14 Mr. Sipes' questions, but I think you said that in statin  
04:24:56 15 monotherapy, meaning when a patient is just given a statin  
04:25:00 16 drug --

04:25:01 17 A Yes.

04:25:01 18 Q -- that rhabdo also has -- there's also a possibility of  
04:25:05 19 rhabdo; is that correct?

04:25:06 20 A Yes, it's in the prescribing information.

04:25:08 21 Q And what -- the -- the chances of a patient who is on  
04:25:13 22 statin monotherapy getting rhabdo are what?

04:25:17 23 A It's low, it's below 1 percent.

04:25:19 24 Q And is that also true of Tricor, the fenofibrate drug?

04:25:22 25 A Yes.

04:25:23 1 Q Has the fact that statin monotherapy can, at least  
04:25:30 2 theoretically, cause rhabdo in a patient, has that deterred  
04:25:36 3 anyone from prescribing statin drugs to patients in need  
04:25:41 4 thereof?

04:25:41 5 A Only when someone has a history of having that, you --  
04:25:47 6 you have to be cautious and not use it.

04:25:51 7 But in terms of if we go primary, secondary  
04:25:54 8 prevention, use the same terminology in a primary population,  
04:25:58 9 a population that has not had rhabdomyolysis, then the  
04:26:04 10 consideration not to prescribe it to avoid that complication  
04:26:08 11 is not -- is not there.

04:26:10 12 Q And the number of patients who are on statin monotherapy  
04:26:15 13 in the United States, is that a large number or a small  
04:26:17 14 number?

04:26:18 15 A Millions of people.

04:26:19 16 Q Now, another thing that Dr. -- I'm sorry, I'm used to  
04:26:26 17 doctors -- Mr. Sipes asked you about, I think he directed you  
04:26:29 18 to the 2019 ADA guidelines and to some language in the ADA  
04:26:33 19 guidelines that have some language in it about -- actually,  
04:26:41 20 let me -- he was asking you some questions about what the ADA  
04:26:46 21 recommends with respect to -- I think it was -- it may have  
04:26:48 22 been fibrate drugs or it may have been Lovaza.

04:26:52 23 But just to be clear, and, again, I think you said  
04:26:54 24 this during your direct examination, the ADA -- and I'm  
04:26:58 25 talking now about the population that is discussed in the

04:27:01 1 claims in this case which is limited to this very high  
04:27:05 2 triglyceride population?

04:27:05 3 A Yes.

04:27:06 4 Q Has the ADA taken any position on whether Vascepa should  
04:27:11 5 be prescribed to that group as opposed to Lovaza or fibrates?

04:27:17 6 A No, we saw on the excerpt during my direct testimony that  
04:27:21 7 they still list fibric acid and/or fish oils for that  
04:27:30 8 population.

04:27:30 9 Q Okay. And I believe in this context Mr. Sipes made  
04:27:34 10 reference to the fact that in a recent update to the  
04:27:39 11 guidelines that the ADA has now recommended that physicians  
04:27:44 12 consider treating patients in the high triglyceride group,  
04:27:49 13 where cardiac risk is the primary focus, on Vascepa; is that  
04:27:53 14 correct?

04:27:53 15 A That is correct.

04:27:54 16 Q And that's as a result of the REDUCE-IT trial.

04:27:57 17 A Definitely.

04:27:58 18 Q But, again, that recommendation is not for the very high  
04:28:02 19 triglyceride category, is it?

04:28:04 20 A They did not include it in that category.

04:28:07 21 MS. HUTTNER: Now, can I have PX 272, please?  
04:28:16 22 Actually, before we do that, can I have -- I think it's the  
04:28:22 23 Vascepa label is DX 2248, and if you could go to the  
04:28:29 24 indications and usage section.

04:28:43 25 Excuse me one second.

04:29:08 1 I'm sorry, Your Honor, I think I need to go to  
04:29:11 2 the old label. Mr. Sipes, do you have the number of the  
04:29:14 3 exhibit you were asking about?

04:29:22 4 MR. SIPES: 940, PX 940 -- hang on.

04:29:26 5 Yes, 940. That's the 2017 label.

04:29:32 6 MS. HUTTNER: Mr. Gross, could you pull up  
04:29:36 7 PX 940. Yeah, if can you go to the next page to the -- and  
04:29:37 8 can you blow up the usage indications section there?

04:29:59 9 BY MS. HUTTNER:

04:29:59 10 Q Okay. And this is the original label for Vascepa,  
04:30:01 11 correct?

04:30:02 12 A Yes.

04:30:02 13 Q So there's only one indication on this label.

04:30:06 14 A Yes.

04:30:06 15 Q And that's for the reduction of triglycerides as an  
04:30:13 16 adjunct to diet in adult patients with severe  
04:30:18 17 hypertriglyceridemia, right?

04:30:20 18 A Yes.

04:30:20 19 Q Now, this language I think that Mr. Sipes directed you  
04:30:34 20 to under usage considerations?

04:30:37 21 A Yes.

04:30:37 22 Q "Patient should be placed on an appropriate  
04:30:41 23 lipid lowering diet and exercise regimen before  
04:30:42 24 receiving Vascepa."

04:30:44 25 I think -- you know, do you understand this to be an

04:30:47 1 instruction that Vascepa should only be given after some --  
04:30:53 2 you know, some nonzero period of diet and exercise?

04:30:58 3 A Can you rephrase that?

04:31:00 4 Q Yeah, in other words, testified in your practice when  
04:31:02 5 patients come in with very high triglycerides that you give  
04:31:05 6 them the drug -- you give them diet and exercise advice and  
04:31:08 7 make appointments to facilitate that, but that you write the  
04:31:13 8 prescription when you see the patient.

04:31:14 9 A Yes.

04:31:15 10 Q And you do that because you are concerned medically that  
04:31:18 11 if you tell the patient to go clean up their life, and they  
04:31:21 12 suffer an attack of pancreatitis, that that's going to be  
04:31:25 13 problematic?

04:31:26 14 A Yes, just like Dr. Sheinberg testified.

04:31:30 15 Q And in terms of Dr. Sheinberg's testimony, were you here  
04:31:35 16 when he testified about his understanding of the original  
04:31:39 17 Vascepa label?

04:31:39 18 A Yes.

04:31:40 19 Q And do you agree or disagree with his reading of the  
04:31:44 20 language?

04:31:44 21 MR. SIPES: Objection, Your Honor. This is  
04:31:45 22 totally outside the scope, it's so open ended. Which portion  
04:31:49 23 of the label?

04:31:51 24 MS. HUTTNER: This portion that we're looking  
04:31:53 25 at.

04:31:53 1 BY MS. HUTTNER:

04:31:53 2 Q Dr. Sheinberg -- do you recall that Dr. Sheinberg  
04:31:55 3 testified about his understanding of the indications and usage  
04:32:00 4 section on the Vascepa label?

04:32:02 5 A Yes, I remember he testified.

04:32:04 6 Q Okay. And specifically he testified about how he  
04:32:08 7 understands Vascepa is to be used, do you recall that?

04:32:10 8 A Yes.

04:32:11 9 Q And do you agree with his testimony, his reading of the  
04:32:14 10 label?

04:32:15 11 A Yes. I think he and I have similar opinions.

04:32:30 12 MS. HUTTNER: Can we go now to the new label,  
04:32:39 13 which is DX 2248, I believe. And can we go to -- yes. Can  
04:32:47 14 you blow up the indications and usage section?

04:32:50 15 BY MS. HUTTNER:

04:32:54 16 Q And if we look at the second indication, which is the  
04:32:57 17 original indication, correct?

04:32:59 18 A Yes.

04:32:59 19 Q And is the language about diet and exercise, that Vascepa  
04:33:07 20 should be given after diet and exercise, has that language  
04:33:11 21 been deleted from the label?

04:33:13 22 A I don't see any mention of exercise here.

04:33:15 23 Q Do you see any -- okay. Do you see any indication that  
04:33:19 24 diet should be modified before Vascepa is prescribed?

04:33:23 25 A No, it says as an adjunct without specifying the order or

04:33:30 1 the timing.

04:33:31 2 Q Okay. Can we go now to -- well, let me ask you one more  
04:33:39 3 question about this.

04:33:39 4 I think Mr. Sipes pointed you to the first  
04:33:43 5 indication on the new label, the cardiac indication?

04:33:46 6 A Yes.

04:33:47 7 Q And I think he pointed you to the fact that it -- the  
04:33:51 8 indication applies to adult patients with el -- I'm sorry,  
04:33:55 9 elevated triglyceride levels above -- equal to or greater than  
04:34:00 10 150 milligrams per deciliter, correct?

04:34:02 11 A Yes.

04:34:02 12 Q And I think he noted or asked you to confirm that there's  
04:34:06 13 no upper end of that range in this label?

04:34:09 14 A Correct.

04:34:09 15 Q Are you aware of whether there was any discussion at FDA,  
04:34:16 16 either the advisory committee, or at the FDA itself, any  
04:34:21 17 determination made that REDUCE-IT shows anything -- shows  
04:34:26 18 positive cardiac benefits with respect to patients in the very  
04:34:30 19 high triglyceride bucket?

04:34:31 20 MR. SIPES: Objection, Your Honor. There's no  
04:34:33 21 foundation for what he knows about FDA's discussions.

04:34:36 22 THE COURT: I agree, and the question is  
04:34:37 23 extremely broad. It assumes his intimate awareness of the  
04:34:42 24 internal discussions of the FDA.

04:34:44 25 MS. HUTTNER: Let me ask you this --

04:34:45 1 THE COURT: And no offense to Dr. Fisher, I'm  
04:34:47 2 sure you're very knowledgeable, but I haven't heard testimony  
04:34:49 3 as to your practice before the FDA.

04:34:49 4 BY MS. HUTTNER:

04:34:55 5 Q Okay. Well, have you -- do you have any knowledge of the  
04:34:58 6 FDA's process for approving drugs?

04:35:00 7 A It's superficial.

04:35:02 8 Q Okay. Fair enough.

04:35:03 9 A I have to admit.

04:35:03 10 Q Fair enough.

04:35:04 11 A The judge hit it on the nail.

04:35:09 12 Q That's why she's the judge.

04:35:10 13 Okay. But as far as the REDUCE-IT study goes, is  
04:35:13 14 there any question in your mind that it does not address the  
04:35:16 15 question of whether or not Vascepa provides cardiac benefits  
04:35:20 16 to patients in the very high triglyceride bucket?

04:35:22 17 A I did not see evidence in that study to support that so I  
04:35:27 18 would be interested now, actually, going to read how the FDA  
04:35:32 19 reasoned for that because in the publically -- in the  
04:35:36 20 published information, I didn't see a basis to reach that  
04:35:40 21 conclusion.

04:35:41 22 Q Okay. Let's go to DDX 6.57. This is an exhibit I think  
04:35:51 23 that was used with Dr. Heinecke.

04:35:55 24 And this is -- DDX 657, you may recall, Dr. Heinecke  
04:36:00 25 testifying about this --

04:36:01 1 MR. SIPES: Your Honor, this is entirely outside  
04:36:03 2 the scope. This is about a label that hasn't been discussed  
04:36:06 3 either in direct or in cross.

04:36:08 4 MS. HUTTNER: It goes directly to the issue --  
04:36:11 5 Mr. Sipes asked questions -- he basically suggested that  
04:36:14 6 because there's no upper indication on the Vascepa label, that  
04:36:18 7 it should be limited to people below 500, that therefore it  
04:36:22 8 applies to people above 500. The Epadel label says exactly  
04:36:28 9 the same thing.

04:36:29 10 MR. SIPES: Your Honor, first of all, this is  
04:36:30 11 Japanese label. I'm not sure --

04:36:31 12 THE COURT: I understand that. So how does this  
04:36:33 13 relate to the question relating to Vascepa?

04:36:37 14 MS. HUTTNER: So the point is if one -- if one  
04:36:38 15 can read the lack of an upper limit on an indication on a  
04:36:43 16 label to mean that a regulatory body has determined that it  
04:36:47 17 provides results in that population, the same is equally true  
04:36:51 18 of Epadel.

04:36:52 19 THE COURT: But Epadel was a different  
04:36:54 20 regulatory body.

04:36:56 21 MS. HUTTNER: Epadel was in fact a different  
04:36:59 22 regulatory body.

04:36:59 23 THE COURT: And I think Dr. Fisher testified  
04:37:03 24 it's still not approved for use in the United States.

04:37:04 25 MS. HUTTNER: That is correct.

04:37:05 1 THE COURT: All right. The objection is  
04:37:07 2 sustained.

04:37:27 3 Dr. Fisher, it was a good thing we took a break.

04:37:30 4 THE WITNESS: Yeah, I'm back to drinking water.

04:37:33 5 MS. HUTTNER: Mr. Sipes asked you -- if I could  
04:37:37 6 have PX 0373.

04:37:37 7 BY MS. HUTTNER:

04:37:45 8 Q Do you recall Mr. Sipes asking you some questions about  
04:37:49 9 this article?

04:37:50 10 A I do.

04:37:51 11 Q And I want to direct your attention to page -- it's  
04:38:01 12 page 1358 of this article under the caption omega-3 Fatty  
04:38:01 13 Acids.

04:38:08 14 MS. HUTTNER: Can you bring that up, Mr. Gross?  
04:38:13 15 It's on 0014. Thank you.

04:38:13 16 BY MS. HUTTNER:

04:38:22 17 Q This is a section of the article that is discussing  
04:38:25 18 omega-3 fatty acids, correct?

04:38:27 19 A Yes.

04:38:27 20 Q And if I can direct your attention to the second  
04:38:31 21 paragraph, it says,

04:38:32 22 "Their outcome benefits for omega-3 fatty  
04:38:34 23 acids have been reported but relate to lower doses  
04:38:38 24 than required clinically to lower triglycerides."

04:38:41 25 And it gives some references, and one of the

04:38:43 1 references that it gives, if you look in -- if we can go to  
04:38:47 2 page -- I believe it's at 22. We can go to reference 224.

04:39:05 3 A Yes, the JELIS study.

04:39:06 4 Q Yes, one of the references that you cite to here is the  
04:39:09 5 Yokoyama article which discusses the JELIS study, correct?

04:39:14 6 A Yes.

04:39:15 7 Q And it goes on to say in that same paragraph, if we go  
04:39:22 8 back to page 14, it says,

04:39:31 9 "These benefits may be explained by  
04:39:33 10 antiarrythmic effects independent of triglyceride,"  
04:39:40 11 correct?

04:39:40 12 A Yes.

04:39:46 13 MS. HUTTNER: Excuse me, Your Honor.

04:39:46 14 BY MS. HUTTNER:

04:39:57 15 Q What does that sentence mean? Can you explain what that  
04:40:00 16 means?

04:40:00 17 A Well, they're saying there have been outcome benefits for  
04:40:05 18 omega-3 fatty acids, but they do not seem to be related to  
04:40:12 19 lowering triglycerides. They must be from another factor, one  
04:40:17 20 that they hypothesize here is antiarrythmic effects.

04:40:23 21 Q By the way, you testified -- you gave some testimony  
04:40:26 22 during direct testimony, and Mr. Sipes asked you about it on  
04:40:30 23 cross, about -- you gave testimony on direct that you didn't  
04:40:33 24 see any evidence in the REDUCE-IT article by Dr. Bhatt that  
04:40:39 25 triglyceride lowering played any role in driving the cardiac

04:40:44 1 benefits in REDUCE-IT. Do you recall that?

04:40:46 2 A I recall that.

04:40:47 3 Q And did -- did the JELIS study reach any conclusion about  
04:40:50 4 whether or not triglyceride lowering played a role in the --  
04:40:55 5 the reduction of cardiac risk?

04:40:58 6 A I do not recall their attributing the results to  
04:41:04 7 triglyceride lowering.

04:41:06 8 Q And in either the Bhatt article or elsewhere, have you  
04:41:12 9 seen any evidence that suggests to you that the cardiac  
04:41:17 10 benefits observed in REDUCE-IT were due to the methods of  
04:41:21 11 lowering triglycerides described in the asserted claims in  
04:41:26 12 this case?

04:41:27 13 A No.

04:41:27 14 (Discussion held off the record.)

04:41:27 15 BY MS. HUTTNER:

04:41:27 16 Q And your answer, sir, was?

04:41:29 17 A Was no.

04:41:32 18 MS. HUTTNER: Nothing further, Your Honor.

04:41:35 19 Your Honor, I don't know -- well, I'll wait  
04:41:38 20 until you excuse Dr. Fisher.

04:41:40 21 MR. SIPES: Uh --

04:41:41 22 MS. HUTTNER: I'm sorry, I'm sorry.

04:41:42 23 MR. SIPES: Do I get to ask questions, too?

04:41:45 24 MS. HUTTNER: You do, you do. I do not have  
04:41:48 25 eyes in the back of my head unfortunately.

RECROSS-EXAMINATION

BY MR. SIPES:

Q The doses of omega-3 fatty acids that are used for lowering triglycerides are 2 or 4 grams, correct?

A Yes.

Q Okay. Now, let's take a look at what you were just asked about, which is PX 373. That's your article from 2011.

And I want to go to the sentence that I think your counsel just suggested was discussing JELIS among other things. So that's on PX 373 at 0014.

And you'll notice --

MR. SIPES: And if you could blow up the -- under omega-3 fatty acids, the first sentence in the second paragraph, Mr. Brooks, and you can have the second sentence, too, just for completeness.

BY MR. SIPES:

Q So, this reads,

"Outcome benefits for omega-3 fatty acids have been reported but relate to lower doses than required clinically to lower triglycerides."

Do you see that?

A Yes.

Q And it cites a number of articles which relate to a variety of omega-3 studies, JELIS on EPA, but also some studies on mixtures, correct?

04:42:56 1 A Yes.

04:42:57 2 Q And so it's lumping EPA and the other omega-3 mixtures  
04:43:03 3 together, correct?

04:43:03 4 A It's not differentiating between the two.

04:43:06 5 Q And lower doses than those clinically required to lower  
04:43:09 6 triglycerides would be below 2 grams. It would be like one,  
04:43:13 7 one and-a-half grams or so, correct?

04:43:15 8 A Not taking into account the blood levels from the natural  
04:43:19 9 sources.

04:43:19 10 Q It's not. It's saying the doses that are being reported  
04:43:24 11 are doses that are well below 4 grams, correct?

04:43:27 12 A Yes.

04:43:28 13 Q And there's no suggestion of raising the dose in this  
04:43:33 14 paper, correct?

04:43:35 15 A I didn't understand that.

04:43:36 16 Q The paper -- you don't suggest in the paper taking EPA  
04:43:41 17 and administering higher doses for cardiovascular benefits,  
04:43:44 18 correct?

04:43:44 19 A That's not mentioned here.

04:43:46 20 Q And, in fact, based on everything, the conclusion was,  
04:43:49 21 for cardiovascular benefits, it's niacin or fibrates, correct?

04:43:55 22 A Yes, on that grid you showed.

04:43:57 23 Q Yeah. And the conclusion was that there was insufficient  
04:44:00 24 evidence for use of omega-3 fatty acids in combination with  
04:44:05 25 statins for cardiovascular benefit, correct?

04:44:08 1 A That's what was stated there, yes.

04:44:10 2 Q Now, I just want to make sure because I think the  
04:44:12 3 testimony got little confused, you recall your counsel took  
04:44:15 4 you back for the labeling for Vascepa and particularly the  
04:44:18 5 indications section.

04:44:20 6 MR. SIPES: So if we could pull up -- so let's  
04:44:20 7 first pull up the old labeling, which is PX 940.

04:44:20 8 BY MR. SIPES:

04:44:23 9 Q And if we look there, there was the usage consideration,  
04:44:29 10 "Patients should be placed on an appropriate  
04:44:31 11 lipid-lowering diet and exercise regimen before  
04:44:34 12 receiving Vascepa and should continue this diet and  
04:44:37 13 exercise regimen with Vascepa."

04:44:39 14 Do you see that?

04:44:40 15 A I do.

04:44:41 16 Q And then, in your report you point to this section among  
04:44:46 17 others in the labeling for your opinion that prescribing  
04:44:49 18 Vascepa without first placing a patient on an appropriate  
04:44:53 19 lipid-lowering diet would therefore constitute an off-label  
04:44:58 20 use of Vascepa, correct?

04:44:59 21 A Technically speaking, yes.

04:45:02 22 Q And that was the opinion you expressed in your report,  
04:45:04 23 correct?

04:45:04 24 A Yes.

04:45:05 25 Q Now, I think you testified that this usage consideration

04:45:07 1 was removed from the labeling, correct?

04:45:11 2 A The -- that exact phrasing, including the exercise  
04:45:19 3 regimen, is not -- was not in the --

04:45:28 4 Q New label.

04:45:28 5 A Yeah, the portion that we were discussing.

04:45:31 6 MR. SIPES: The portion -- it's helpful to look  
04:45:32 7 at the whole labeling, so why don't we pull up 1186, the  
04:45:36 8 current Vascepa labeling.

04:45:38 9 And it's been moved from the indication and  
04:45:39 10 usage section, but if we could pull up section 2.1. If you  
04:45:44 11 could blow that up, Mr. Brooks, section 2.1.

04:45:44 12 BY MR. SIPES:

04:45:48 13 Q So this is the dosage and administration section of the  
04:45:50 14 Vascepa labeling, correct?

04:45:52 15 A Yes.

04:45:52 16 Q And it says, section 2.1, prior to initiation of Vascepa,  
04:45:57 17 correct?

04:45:57 18 A Yes, it does.

04:45:58 19 Q So the labeling in the dosage and administration section  
04:46:01 20 says what to do before start Vascepa, correct?

04:46:03 21 A Uh-huh, yes.

04:46:05 22 Q The second bullet says specifically,

04:46:07 23 "Patients should engage in appropriate  
04:46:08 24 nutritional intake and physical activity before  
04:46:11 25 receiving Vascepa which should continue during

04:46:14 1 treatment with Vascepa," correct?

04:46:15 2 A Yes.

04:46:15 3 Q So all the FDA has done is moved that language from the  
04:46:21 4 indication and usage section to the dosage and administration  
04:46:22 5 section, correct?

04:46:22 6 A That is correct.

04:46:23 7 Q Okay. And your counsel asked you whether your  
04:46:29 8 understanding of the indication was the same as  
04:46:33 9 Dr. Sheinberg's. Do you recall that question?

04:46:34 10 A Yes.

04:46:35 11 Q And the indication we're talking about that's -- let's go  
04:46:41 12 to the indication section. And the indication we're talking  
04:46:46 13 about here is not the CV risk indication, we're talking about  
04:46:49 14 the severe hypertriglyceridemia indication, right?

04:46:53 15 MR. SIPES: Let's blow that up. That's the  
04:46:53 16 second indication now on the label.

04:46:53 17 BY MR. SIPES:

04:46:55 18 Q All right. That was the indication that you were  
04:46:57 19 agreeing with Dr. Sheinberg about, right?

04:46:59 20 A Yes.

04:47:00 21 Q In fact, it's your testimony that the indication of  
04:47:05 22 Vascepa is for keeping triglycerides below 500 milligrams per  
04:47:10 23 deciliter in a severely hypertriglyceridemic patient, correct?

04:47:13 24 A I certainly -- the indication is to get the triglycerides  
04:47:18 25 below 500.

04:47:20 1 MR. SIPES: Mr. Brooks, if we could play  
04:47:23 2 deposition 72 at 3 through 8.

04:47:32 3 (Deposition video recording played.)

04:47:45 4 BY MR. SIPES:

04:47:46 5 Q And, in fact, it's -- so it was your testimony at  
04:47:52 6 deposition that in fact the indication is to reduce below 500  
04:47:56 7 and to maintain that reduction below 500, correct?

04:47:58 8 A In many patients, yes.

04:48:00 9 MR. SIPES: No further question, Your Honor.

04:48:02 10 MS. HUTTNER: I have nothing further, Your  
04:48:06 11 Honor.

04:48:06 12 THE COURT: Well, thank you, Dr. Fisher. You  
04:48:08 13 may step down.

04:48:09 14 THE WITNESS: Thank you. First I have to stand  
04:48:11 15 up.

04:48:13 16 MS. HUTTNER: That's the hard part.

04:48:15 17 THE COURT: Quite true.

04:48:26 18 (The witness was excused.)

04:48:26 19 MS. HUTTNER: Your Honor, at this point, our  
04:48:29 20 intention would be to call our next witness which is another  
04:48:33 21 expert witness named Ivan Hoffman. He addresses commercial  
04:48:39 22 success.

04:48:39 23 And I don't know whether you want to start now  
04:48:41 24 or whether you want to defer until Tuesday.

04:48:47 25 MR. SIPES: Your Honor, I may be able -- I won't

04:48:51 1 speak for defendants, I believe we're proceeding at a pretty  
04:48:53 2 good clip, in other words, we are a little ahead of at least  
04:48:58 3 of where I expected so that we will finish in time, I believe.  
04:49:01 4 Defendants will let me know if they disagree.

04:49:04 5 And we may have a scheduling issue on Tuesday.  
04:49:07 6 We have witnesses who can go, but I've been informed one of  
04:49:09 7 the witnesses we were planning to bring on Tuesday may, may  
04:49:12 8 have a childcare issue.

04:49:13 9 Now, I don't think -- we have other witnesses  
04:49:16 10 that we would bring but -- so that I think we will have a good  
04:49:18 11 day on Tuesday, but we might not have a completely full day on  
04:49:22 12 Tuesday. So deferring Mr. Hoffman to Tuesday I don't think  
04:49:24 13 would cause a problem.

04:49:25 14 MS. HUTTNER: I think, Your Honor, defendants  
04:49:27 15 would agree with that.

04:49:28 16 I suspect given the pace of the way the  
04:49:30 17 witnesses have been going, and Mr. Sipes and I had a  
04:49:34 18 discussion about it, that -- assuming that Mr. Hoffman doesn't  
04:49:35 19 start today, that we would have our commercial success expert,  
04:49:42 20 as well as their commercial success expert, as well as I think  
04:49:47 21 two fact witnesses, Mr. Berg and Ms. Juliano.

04:49:53 22 MR. SIPES: It's Ms. Juliano who has the  
04:49:55 23 problem.

04:49:56 24 MS. HUTTNER: Or Mr. Peck, who is the FDA --

04:49:59 25 MR. SIPES: Dr. Peck.

04:50:00 1 MS. HUTTNER: It's very confusing.

04:50:02 2 But I think we'll have enough witnesses to fill  
04:50:04 3 the day on Tuesday, although at least to get through most of  
04:50:09 4 the day.

04:50:09 5 So I -- I think if we stop now we will not lose  
04:50:13 6 anything in terms of being able to complete the trial on time.

04:50:17 7 THE COURT: Ms. Huttner, I'm mindful of the fact  
04:50:19 8 you that you had asked for us to recess on Tuesday because you  
04:50:22 9 indicated you had concerns about some of the -- the schedule  
04:50:24 10 of one of your witnesses. Has that been resolved?

04:50:28 11 MS. HUTTNER: Yes, the witness was actually  
04:50:30 12 Dr. Fisher, and my concern was, if I couldn't start him on  
04:50:34 13 Friday, if he couldn't finish his testimony on Friday, he  
04:50:35 14 would have a problem -- we would have an empty day in between.  
04:50:39 15 So that problem is no longer an issue.

04:50:41 16 MR. SIPES: And the only other issue is we have  
04:50:42 17 agreed not to call the witnesses he responds to on Tuesday,  
04:50:46 18 but there's plenty of other witnesses so it's not issue.

04:50:49 19 THE COURT: All right. Then basically you both  
04:50:50 20 agree I should take a recess for today.

04:50:52 21 MS. HUTTNER: I think we're agreeing.

04:50:54 22 MR. SIPES: I confess to being a little bit  
04:50:54 23 brain addled, too.

04:50:55 24 MS. HUTTNER: It may be historic, Your Honor,  
04:50:56 25 and it should be respected.

04:50:58 1 THE COURT: We'll take a recess. But, first, I  
04:51:01 2 have an observation about the issue of sealed filings, and  
04:51:04 3 this is why I had expressed my concern over the course of  
04:51:09 4 several orders now as to the generosity in which the documents  
04:51:13 5 were designated as confidential.

04:51:15 6 For example, just in my quick viewing of two  
04:51:19 7 exhibits that were not actually admitted, they were marked,  
04:51:22 8 492 and 949, during Dr. Fisher's cross-examination these are  
04:51:29 9 other articles that, Mr. Sipes, you asked Dr. Fisher about  
04:51:33 10 relating to other studies.

04:51:35 11 So to me they look like all the other studies,  
04:51:37 12 and yet they're designated as highly confidential, and I don't  
04:51:42 13 know why they would be designated as highly confidential.

04:51:45 14 So I'm not asking you to explain, I'm just  
04:51:47 15 making -- I think that's further support for my observation  
04:51:50 16 that there's been an over-extensive designation of  
04:51:54 17 confidential documents. So when comes time for redaction, I  
04:51:57 18 want you to be aware that I -- I'm going to scrutinize it.

04:52:00 19 All right. So we're ready to take our recess.  
04:52:03 20 Have a good three-day weekend, hopefully you won't be working  
04:52:06 21 too much over the course of the three-day weekend --

04:52:10 22 MS. HUTTNER: You don't really believe that,  
04:52:11 23 Your Honor.

04:52:11 24 THE COURT: Well, Reno is beautiful this time of  
04:52:14 25 the year so at least I hope you get a chance to enjoy it.

04:52:18

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Thank you.

MS. HUTTNER: Thank you, Your Honor.

MR. SIPES: Thank you, Your Honor.

-o0o-

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/Kathryn M. French 1/30/2020  
Kathryn M. French, CCR #392, RPR  
Official Reporter

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